Thomas J. Kowalski
is a partner in the New York office of Frommer Lawrence & Haug LLP.

Antonio Maschio, PhD
is a partner in the Southampton, UK, office of D. Young & Co.

Samuel H. Megerditchian
is an associate in the New York office of Frommer Lawrence & Haug LLP.

Dominating global intellectual property: Overview of patentability in the USA, Europe and Japan

Thomas J. Kowalski, Antonio Maschio and Samuel H. Megerditchian

Date received (in revised form): 17th March, 2003

Abstract

The USA, Europe and Japan dominate intellectual property. The patent offices of these three economies issue the vast majority of the world's patents and harmonisation has been a key initiative in recent years. Corporate and academic leaders, inventors and practitioners should be aware of the examination practices in all three patent offices.

The opinions expressed herein are the personal opinions of the authors, and are not to be considered the opinions of Frommer Lawrence & Haug LLP, D. Young & Co. or any of the firms' clients. Further, nothing in this paper is to be construed as legal advice, a substitute for legal advice, or as positions/strategies etc taken/employed in, or suitable for, any particular case or set of facts.

Keywords: *USPTO, EPO, JPO, patents, harmonisation, patentability, trilateral initiative*

Thomas Kowalski
Frommer Lawrence & Haug LLP,
New York Office,
745 Fifth Avenue,
New York, NY 10151, USA

Tel: +1 212 588 0800
Fax: +1 212 588 0500
E-mail: tkowalski@flhlaw.com

It is unquestionable that the USA, Europe and Japan dominate the intellectual property (IP) landscape. Indeed, statistics show that the patent offices of these pillars (the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the Japan Patent Office (JPO), respectively) issue nearly 90 per cent of the world's patents.[1]

It is not coincidental, however, that the patent offices of the three most powerful global economies issue the most patents. The consensus among corporate, academic and political leaders throughout the USA, Europe and Japan has long been that IP is an extraordinarily valuable asset: one that not only significantly affects revenue, but also directly influences shareholder value and academic prestige. Additionally, since a patent is an enforceable privilege of limited duration, the corporate and academic elite readily understands that a well-prosecuted patent portfolio affords considerable strategic leverage in the marketplace, especially if the patents are directed to pioneering technologies in the pharmaceutical or biotechnology sectors.

Therefore, the public has a vested interest in understanding the examination practices of all three patent offices. And although the three systems essentially share the same basic rules for patentability, both substantive and procedural differences exist. It is the appreciation of these systems that will enable applicants and practitioners to wisely prosecute patent applications.

OVERVIEW OF PATENTABILITY IN THE USPTO, EPO AND JPO

The dominant policy objective of patent law, whether in the USA, Europe or Japan, is the balancing of two conflicting equitable interests: rewarding an inventor by granting patent exclusivity while, simultaneously, stimulating competition in the art in which the patent monopoly falls. The exclusivity enjoyed by the patentee acts as a shield against the unauthorised making, using or selling of

the patented invention for a fixed period of time. Competition, on the other hand, is stimulated in two ways: first, by limiting this exclusivity to the four corners of the patent and, second, by limiting the life of the patent to that fixed term.

In the USA, the USPTO is the government agency responsible for examining patent applications and issuing patents. A patent for an invention is the grant of a property right to the inventor. The property right is personal, in that the patent can be sold, mortgaged, bequeathed to an heir or assigned from one owner to another. The right conferred by the patent to the owner is the right to exclude others from making, using, offering for sale, or selling the invention in the USA or importing the invention into the USA. More specifically, what is granted is *not* the right to make, use, offer for sale, sell or import by the patent owner, but rather the right to exclude others from making, using, offering for sale, selling or importing the patent owner's invention. Once a patent is issued, the patentee must enforce the patent without aid of the USPTO.

Generally, the term of a new patent is 20 years from the date on which the application for the patent was filed in the USA or, in special cases, from the date an earlier related application was filed, subject to the payment of maintenance fees. US patents are effective only within the USA, its territories, and its possessions.

Patentable subject matter

Types of US patents

There are generally three types of US patents: utility, design and plant. Utility patents may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or compositions of matter, or any new useful improvement thereof. A utility patent covers the way something 'works': an apparatus, machine, composition, etc.

A design patent, by contrast, protects the exterior appearance of an article of manufacture, ie the way an invention 'looks'. A picture, a print or an impression, however, are not articles of manufacture and, therefore, unpatentable. The drawings of the design patent constitute the disclosure. All design patents have only a single claim which refers to the drawing. Design patents must satisfy the statutory requirements of patentability (35 USC §§112, 102 and 103) and may also be subject to restriction. The term of a design patent is 14 years from issue.

Plant patents may be granted to anyone who invents or discovers any distinct and new variety of plants. The plant must be invented or discovered in a cultivated state and asexually reproduced.

The USA follows the 'first-to-invent' system, whereby a patent is awarded to the first person to invent the subject matter of the patent application. Europe and Japan, however, follow the 'first-to-file' system. There, a patent is awarded to the first person to file an application to the patent office, even if the filer is not the first inventor.

The USPTO, EPO and JPO, however, essentially follow similar statutory requirements for patentability. To be patentable, a claim must recite patentable subject matter; be useful; adequately described and enabled in the specification; clear; and free from the prior art (ie novel and non-obvious). These requirements are represented in Table 1.

Patentable subject matter/ statutory invention

In the USA, patentable subject is based on Section 101 of Title 35 of the US Code as interpreted by the Federal courts. According to Section 101: 'To be considered patent eligible subject matter under 35 U.S.C. §101, the claimed invention must be a process, machine, manufacture, or composition of matter that has a practical utility.'

Thus, subject matter worthy of a patent includes, for example:

- processes (utility patent);
- apparatus (utility patent);
- articles of manufacture (utility patent);

Table 1: Applicable sections/articles of respective patent laws

	Patentable subject matter/ statutory invention	Industrial applicability/ utility	Enablement/support/ sufficiency/written description and clarity	Novelty/inventive step/ non-obviousness
USPTO	35 USC §101	35 USC §101	35 USC §112, first and second paragraphs	35 USC §§102,103
EPO	EPC Art. 52	EPC Art. 57	EPC Arts. 83, 84	EPC Arts 54,56
JPO	JPL §2(1)	JPL §29 (1)	JPL §36 (4) (6)	JPL §29(1)(2)

Japanese Patent Law

- compositions of matter (utility patent);
- new uses of known processes (utility patent);
- ornamental, non-functional designs for articles of manufacture (design patent);
- asexually produced plants (plant patent);
- biotechnological inventions: eg stem cells (utility patent).

In the EPO, Article 52 of the EPC controls on the issue of patentable subject matter:

EPC

EPC Art.52(1):
European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

EPC Art.52(2):
The following shall not be regarded as inventions within the meaning of paragraph 1:
(a) discoveries, scientific theories and mathematical methods;
(b) aesthetic creations;
(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
(d) presentations of information.

In Japan, the JPO defines patentable subject matter as follows:

Japanese Patent Law Sect. 2(1): Definition of Invention
(Guidelines Part II,Chap.1, 1.) Patent Law Section 2(1) defines a statutory invention as a highly advanced creation of technical ideas utilizing a law of nature.

Utility/industrial applicability

35 USC §101 is the statutory basis for the utility requirement in the USPTO:

> To comply with 35 U.S.C. §101, the claimed invention must have at least one specific, substantial, and credible utility that is either asserted in the specification or is well-established.

An invention must be useful, eg it must solve a problem. Indeed, according to the Supreme Court, 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.'[2] Although mechanical and electrical inventions readily satisfy the requirement, pharmaceutical and biotechnological inventions may pose difficulties.

The requirements for utility and enablement are closely related. According to *In re Swartz*,[3] where the Federal Circuit held that a claim to cold fusion failed both the utility and enablement requirements, the court explained:

> 'The question of whether a specification provides an enabling disclosure under Section 112, paragraph 1, and whether an application satisfies the utility requirement of Section 101 are closely

related.' In order to be enabling, a patent specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. Under Section 101, any patentable invention must be useful and, accordingly, the subject matter of the claim must be operable. As a result, if the claims in a patent application fail to meet the utility requirement because they are either not useful or inoperative, they will also fail to meet the enablement requirement.[4]

The utility requirement finds support in both 35 USC §§101 and 112:

An invention must be useful

- 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'.

- 35 USC 112: '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.'

Utility Examination Guidelines

The USPTO, in an effort to better quantify the utility requirement, published its Utility Examination Guidelines at 66 FR 109 (5th January, 2001); 1242 OG 162 (30th January, 2001). The PTO presents a three-prong test: specific, substantial and credible utility must be asserted in the specification. More specifically, according to the USPTO, an invention has a well-established utility if:

- a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (eg properties or applications of a product or process), and

- the utility is specific, substantial and credible.

In other words:

- Specific utility: specific utility for the *claimed* invention.

- Substantial utility: utility that has real world value.

- Credible utility: Would an artisan accept that the disclosed invention is in currently available form? Lack of credible utility normally arises where the invention is inoperative or would not be expected to function in the disclosed manner based upon current scientific understanding.

Using a specific example, assume a claim to 'An isolated nucleic acid comprising SEQ ID No. 1' where

- the nucleic acid does not encode an identified protein, and no particular target of diagnostic relevance is disclosed ('1st generation expressed sequence tag, EST'), or

- the nucleic acid encodes a protein whose function is inferred by homology ('2nd generation EST', and either assignment of function is rebuttable or assignment of function lacks sufficient specificity to establish a specific, substantial, substantial, credible utility (eg assignment as 'IL receptor' would not be sufficient).

Such a claim may *not* comply with the utility requirement.

Assume further a claim to a receptor where neither the receptor nor its ligand has specific, substantial and credible utility, and the receptor function cannot be predicted from DNA or protein

sequence homology. Where the receptor protein does not meet the utility requirement, claims directed to the following also do not comply with the utility requirement:

- screening methods using the receptor;
- ligands/agonists/antagonists in general identified by the screening methods;
- methods, uses or medicaments utilising the ligands/agonists/antagonists in general;
- methods, uses or medicaments utilising specific ligands/agonists/antagonists; and
- antibodies that recognise the receptor.

The EPO follows EPC Art. 57, which sets forth the industrial application requirement:

> An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

Examination guidelines in the EPO

The Guidelines for Substantive Examination of the EPO, at C-IV 4.6, comment on Art. 57:

> In general it is required that the description of a European patent application should, where this is not self-evident, indicate the way in which the invention is capable of exploitation in industry. In relation to sequences and partial sequences of genes this general requirement is given specific form in that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. A mere nucleic acid sequence without indication of a function is not a patentable invention. . .

Current practice in the examining divisions of the EPO considers that there are three categories for alleged function: General or 'throw away', intermediate and specific. Examples of general function include 'secreted protein' and 'for feeding'. An example of an intermediate function is 'receptor'. An example of a specific function is 'epitope with unique activity'. In the EPO system, general and intermediate functions are typically not considered to be inventive as being arbitrary selections from the prior art.

In the EPO, the initial burden for demonstrating a lack of function rests with the examiner. However, if the examiner can raise substantiated doubts concerning an asserted function, the burden is on applicants to establish the alleged function. To this end, applicants should be aware that:

- *in silico* evidence is acceptable;
- credibility may be established by documents or experimental evidence;
- technical arguments brought in support of patentability must have been foreshadowed in the application; and
- wish lists do not properly indicate nor foreshadow a technical problem or solution thereto.

The decision of the Opposition Division of the EPO in the case of European Patent 0630405 (Icos) has been published.[5] This decision illustrates the thinking of the Examining and Opposition Divisions in matters relating to current practice in connection with the requirement for function.

The Opposition Division stated, in this decision:

> The disclosure of a predicted function of a protein in combination with a method of verification of this function is not necessarily adequate to sufficiently disclose the function of the protein. In the absence of a disclosed compound (a ligand for a predicted receptor protein), methods utilising this compound (modulating the

> binding of the ligand) are not considered sufficiently disclosed. A list, in the description, of speculative functions of a protein is not in itself a reliable basis for acknowledging industrial application of this protein. A DNA sequence encoding a protein without a credible function is not a patentable invention.

Although the Patent Proprietor did file a Notice of Appeal, no Statement of Grounds for Appeal was filed and the Appeal was thus held inadmissible. The position taken by the Opposition Division has thus not been reviewed at the level of a Board of Appeal.

An invention must be enabled, adequately described and clear

Guidelines in Japan

In Japan, the JPO follows Japanese Patent Law Sect. 29, First Sentence, for industrially applicability. According to the JPL Guidelines, Part VII, Chapter 2, 1.3.1, 'Inventions . . . whose utility is not described in a specification or cannot be inferred, do not meet the requirements set forth in the first sentence in Section 29(1) of the Patent Law.'

Industrial applicability

The Japanese patent system is geared to those inventions that are industrially applicable. Industry is broadly construed to include, for example, mining, agriculture, telecommunications and manufacturing. Commercially inapplicable and, hence, industrially inapplicable, inventions include, for example, an invention applied only for a personal use (eg method of smoking) and an invention applied only for academic or experimental purposes.[6]

Medical treatment

One area of dissimilarity between the patent offices is the patentability of medical treatment. The USA takes a liberal approach, finding that method of treatment to be patentable subject matter. Europe and Japan, by contrast, are more restrictive. The EPO and JPO do not consider methods of medical treatment to be patentable. Indeed, Article 52(4) of the EPC specifically excludes as unpatentable 'methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body.'[7] And in Japan, such methods are considered 'industrially inapplicable' and, thus, unpatentable.[8]

Those countries that exclude medical treatment claims often look favourably at claims directed to a 'use'. Such 'use' claims, commonly referred to as 'Swiss-type claims' or 'second medical use' claims, are directed to the 'use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application.'[9] One disadvantage of such a claim, however, is that the substance's use may be restricted 'to the short term ''acceptable'' industrial application rather than the ultimate therapeutic use.'[10]

Enablement, written description and clarity

According to 35 USC §112, first paragraph, a patent application, to support a claim, *must* enable the claim and *must* adequately describe the subject matter of the claim:

> 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.

Thus, under US law, there are two distinct requirements: the enablement requirement and the written description requirement.

The test for enablement requires a determination of whether any person skilled in the art can make and use the invention without undue experimentation.[11] The factors involved in determining whether there is sufficient evidence to support a finding of enablement include, among others: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6)

the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.[12] Analogously, Europe follows the 'Sufficiency of Disclosure' rule: that the application must disclose the invention in a manner sufficiently clear to be carried out without undue experimentation by a person skilled in the art.[13]

There are two independent components of the enablement requirement in the USA: how to *make* the claimed invention over the scope claimed without undue experimentation (eg 'identifying' a compound via a screening method is not the same as teaching how to 'make' the compound); and how to *use* the claimed invention over the scope claimed without undue experimentation (note, however, that the presence of specific, substantial and credible utility is not by itself sufficient to meet this criterion. Similarly, there are two forms of rejections that an examiner may present during prosecution: full scope claimed, but not enabled for how to make and/or use; and a certain identified portion of scope claimed, but not enabled, ie 'scope of enablement.'

Written description

Turning to the written description requirement, the USPTO provides guidance in its 'Written Description Guidelines.'[14] The Guidelines explain:

> The first paragraph of 35 U.S.C. 112 requires that the 'specification shall contain a written description of the invention.' This requirement is separate and distinct from the enablement requirement. The written description requirement has several policy objectives. '[T]he ''essential goal'' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed.' Another objective is to put the public in possession of what the applicant claims as the invention. The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.
>
> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently, a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c). Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis.[15]

According to the Federal Circuit's predecessor court in *In re Edwards*,[16] the function of the written description requirement is to:

> [E]nsure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; to comply with the description requirement, it is not necessary that the application describe the claimed invention in ipsis verbis; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him.[17]

Thus, one of the goals of the written description requirement is to convey to a skilled artisan that the patentee invented the claimed subject matter. To this end, the specification must convey with clarity to one skilled in the art that the patentee had possession of the invention.[18] Possession may be evidenced, *inter alia*:

- by actual reduction to practice;
- by clear depiction in detailed drawings or structural chemical formulas; and
- through written description describing sufficient relevant identifying characteristics.

Whether there are sufficiently relevant identifying characteristics, in turn, requires weighing a number of factual considerations in view of the level of skill and knowledge in the art. Some factors include:

- complete or partial structure;
- physical and/or chemical properties;
- functional characteristics;
- correlation between structure and function; and
- method of making.

Pharmaceutical/biotech claims

Pharmaceutical and biotechnology claims raise additional issues. The Federal Circuit has noted that an adequate written description of an invention involving genetic material 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials.[19] A mere wish or plan, however, is insufficient.[20]

Indeed, the courts warn that merely providing a name of a molecule, knowing how to make it, and knowing what it does, in a general sense, may not put one in possession of the molecule if the art is unpredictable.[21]

Genus claims are also problematic. For example, to support a claim to a genus requires a representative number of species, or sufficiently relevant identifying characteristics of the genus, for there to be acceptable written description. And there is an inverse correlation between the predictability of the technology and the number of embodiments that must be described; in other words, the less predictable the technology, the more embodiments necessary for compliance with the written description requirement.

Enablement and written description problems

Assume a claim to 'An isolated nucleic acid comprising SEQ ID No. 1 where nucleic acid does not encode an identified protein' (eg a 1st generation EST). Such a claim would:

- probably lack an adequate written description for 'gene' that falls within the scope of the claim;
- probably lack enablement with respect to what additional sequences may be added to those specifically disclosed such that the asserted utility would be present; and
- read on a number of non-enabled embodiments such as protein coding regions, genes and alleles.

Note, however, that broader claim scope in 2nd generation and 3rd generation

DNA claims that would likely be more description and find enabling support in the specification.

Assume general receptor ligand/agonist/antagonist reach-through claims, such as:

- 'a receptor [X] agonist'; or
- 'a product identified by the screening process of claim 1 (wherein claim 1 screens for agonists of receptor [X])'; or
- 'a method of treating disease [Y] by administering a compound which is a receptor [X] agonist' ('functional use' claim to a method of treating a disease by a compound defined not by its structure but rather by its ability to bind to a target).

Such a generic claim to 'A receptor [X] agonist' would probably not comply with written description requirement when:

- there is no description of structure of representative number of claimed compounds; or
- there is no description of chemical or physical characteristics of representative number of claimed compounds or of function of representative number of claimed compounds (other than binding to identified receptor).

Such a scenario is analogous to *Regents of the Univ. of Cal. v Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) (noting that a description of how to obtain compounds is not sufficient without description of what the compounds are).

A generic claim to 'A receptor [X] agonist' is also not likely to comply with enablement requirement when:

- the specification does not teach how to make and use the full scope of agonists or antagonists within that genus without undue experimentation; or
- the specification teaches how to identify compounds, rather than how to make them; the specification does not teach how to use the full scope of the compounds within the genus without undue experimentation.

Thus, consider, instead, other claim strategies to cover downstream products and for breadth, eg business method, transmission of data/information, identification and claiming of novel sequences common to various species of genus, disclosure and claiming of percentage homology + function, filing on 2nd or 3rd generation DNA case rather than 1st generation, claiming vectors, methods for expressing products, methods for making vectors, etc.

Business methods are discussed in greater detail in the section 'Business methods in the USA'.

According to 35 USC §112, second paragraph, a claim *must* be definite:

> The specification shall conclude with one or more claims *particularly pointing out and distinctly claiming* the subject matter which the applicant regards as his invention.

The definiteness requirement forces a patentee to draft claims with clarity and precision.[22] Indeed, Section 112, second paragraph, contains two requirements: first, that the claims be drafted with precision and definiteness and, second, that the claims be directed to the subject matter that the applicant regards as his or her invention.[23]

The Federal Circuit considers compliance to Section 112, second paragraph, necessary to preserve the notice requirement of a patent.[24] The skilled artisan standard is used when analysing claim language for compliance with Section 112, second paragraph.[25] Further, inconsistency with the specification may make a claim take on an unreasonable degree of uncertainty.[26]

EPO

The analogous statues in the EPO for

enablement and clarity are EPC Arts. 83 and 84:

- **EPC Art. 83: Sufficiency of Disclosure**. 'The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art' (Guidelines C-II, 4.9). 'The application must contain sufficient information to enable the person skilled in the art, using his common general knowledge, to perform the invention over the whole area claimed without undue burden and without needing inventive skill.'

- **EPC Art. 84: Clarity and Support**. The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description (Guidelines C-III 6.3). In order to comply with the requirement of Art. 84, there must be sufficient support of technical character in the description that allows to extend the particular teaching of the description to the whole field claimed.

One point of departure from the USPTO system is that the EPO does not have a written description requirement. In other words, the EPO allows for more generalisation than the USPTO.

In general, a claim must be enabled across its whole scope in order to be allowable in the EPO.[27] Notwithstanding this, assessment of enablement in the EPO follows the general principle that the scope of a claim granted for an invention should be commensurate in scope with the technical contribution to the art which the applicant has made.[28] Thus, broad claims may be allowable where the applicant has provided a technical concept, which defines a patentable invention, and which can itself be generalised by the person skilled in the art. In particular, the applicant is permitted to generalise from specific examples, where such generalisation is technically credible and scientifically valid.

JPO

The JPO tracks the EPO system:

- **Japanese Patent Law Sect. 36(4): Description, Enablement** (Guidelines Part VII, Chapter 2, 1.1.2.1). Section 36(4) of the Patent Law states that 'the detailed description of the invention shall be stated . . . in such a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art to which the invention pertains.' For an invention of a product, the definition of 'being able to carry out the invention' is to make and use the product. . .

- **Japanese Patent Law Sect. 36(6): Clarity of Claims** (Guidelines Part VII, Chapter 2, 1.1.1). According to Section 36(6)(ii) of the Patent Law, the invention for which a patent is sought shall be clear, therefore, scope of claim shall be described so that an invention is clearly identified on the basis of statements of each claim.

The JPO considers the following to be an example of a claim failing the clarity requirement: 'A chemical compound that activates the R-receptor'. The JPO explains that if the R-receptor is novel, it is presumed that a skilled artisan is not capable of conceiving the chemical compound that has R-receptor activating abilities. Thus, the claim is unclear.[29]

Turning to enablement, the JPO considers the following claim to be defective: '*Streptomyces griseus* producing antibiotic A'. The applicant's specification noted that a strain of *S. griseus* that produced novel antibiotic A was obtained by artificially mutating *S. griseus* in a specific process. The specification, however, did not contain a statement that the obtained strain was deposited. The JPO would reject the claim as lacking enablement for the failure to officially deposit the microorganism before the

application was filed and for failure of the specification to contain a statement that more than one strain of *S. griseus* producing antibiotic A was obtained in the process in the detailed description of the invention.[30]

Freedom from the prior art

Novelty/obviousness in USPTO

The statutory bases for novelty and non-obviousness in the USPTO are as follows:

- **35 USC §102: Novelty**. A claimed invention complies with the novelty requirement if there is no single reference that expressly, implicitly or inherently describes the invention including each claimed element.

- **35 USC §103: Non-obviousness**. A claimed invention complies with the non-obviousness requirement if there are no prior art references that, alone or in proper combination, teach or suggest the invention as a whole including each element of the claimed invention. In determining whether an invention would have been obvious, the examiner determines the scope and contents of the prior art, ascertains the differences between the prior art and the claims in issue, resolves the level of ordinary skill in the art, and evaluates any objective evidence of non-obviousness.

The analogous statutory sections for novelty and inventive step in the EPO are:

Novelty and inventive step in EPO

- **EPC Art. 54: Novelty.**

- **EPC Art. 54(1)**. An invention shall be considered to be new if it does not form part of the state of the art.

- **EPC Art. 54(2)**. The state of the art shall be held to comprise 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.

- **EPC Art. 56: inventive step**. An invention shall be 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.

In the USA, if a reference identically describes the invention in every detail and each and every element of the invention as claimed, then the reference is said to anticipate the claimed invention.[31] Each claim element must either be expressly or inherently disclosed in a single prior art reference,[32] and must be as arranged as in the claim.[33]

US prior art requirements limit certain types of disclosures to acts within particular geographical limitations, such as territories of the USA, and limit prior art effect depending on from whom prior art originated:

- 35 USC 102(a) – known or used in the USA.

- 35 USC 102(b) – in public use or on sale in the USA.

- 35 USC 102(g) – invention was made in the USA by another who has not abandoned, suppressed or concealed it.

- 35 USC 102(a), (e) – disclosure disqualified from being prior art if not by 'others' or 'another'.

- 35 USC 102(e), (f), (g) – disclosure disqualified if unity of ownership; see 35 USC 103(c).

In the USA, a 'grace period' is recognised, wherein an applicant's own activity or publications will not bar a patent if the US application is filed within a year from the date of activity or publication. In the European patent system, by contrast, 'absolute novelty' controls. In other words, there is no grace period in the EPO. There are no restrictions as to geographical location, language or manner in which information was made available to the public or if

prior art is from same inventor(s)/owners; thus, all kinds of disclosures, wherever in the world, are state of the art.

Unlike anticipation, however, references may be combined to render a claim 'obvious'. But if references are combined, there must be some suggestion (or motivation) to make the combination.[34] In US practice, determining obviousness under 35 USC 103 follows the guidelines set forth in *Graham v John Deere*,[35] and its progeny:

Obviousness approach in USPTO

> Patent may not be obtained if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains; but, patentability shall not be negatived by the manner in which the invention was made.[36]

Thus, for determining 'obviousness,' the four factual inquires enunciated in *Graham* include:

- determine the scope and contents of the prior art;
- ascertain the differences between the prior art and the claims in issue;
- resolve the level of ordinary skill in the pertinent art; and
- evaluate evidence of secondary considerations, eg unexpected results, commercial success, long-felt need, failure of others, copying by others, licensing, scepticism of experts, etc.[37]

Problem/solution approach in EPO

By contrast, the problem-solution approach is uniformly adopted by the EPO and most European countries. This approach involves the steps of:

- determination of the technical problem which the invention seeks to solve;
- determination of the closest prior art; and
- assessment of whether arriving at the solution to the technical problem addressed by the patent or patent application starting from said closest prior art would have been obvious to a person skilled in the art.

With respect to genus/species issues:

- USA – Obviousness of claimed species when genus is in prior art:

  The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.[38]

Consider size of genus, express teachings, teachings of structural similarity, similarity of properties or uses, predictability.

- Europe – inventive step of claimed species when genus is in prior art. Merely selecting particular chemical compounds or compositions from a broad field does not involve an inventive step, unless claimed invention has advantageous properties not possessed by prior art examples or unless claimed invention has unexpectedly advantageous properties compared with the prior art examples.

With respect to genomics:

- USA – Obviousness of protein or nucleic acid encoding the protein. Examiners have a difficult time making a *prima facie* case of obviousness using a prior art nucleic acid or amino acid sequence that differs even slightly from applicant's claimed sequence because motivation for the specifically claimed change must be shown: (a) *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995); (b) *In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993). Exceptions may include degenerate codon substitutions or some

conservative amino acid substitutions, cysteine replacements, etc, if such substitutions are shown to be functional equivalents in the art in the same context.

- EPO – *T939/92, 'AgrEvo'*. In the absence of a credible function for a claimed compound, the problem to be solved is merely the provision of an arbitrary new compound. Hence, a genomic sequence can only be inventive if a specific and credible function has been disclosed.

The EPO applies a stringent inventive step analysis to claims. In other words, according to the EPO, a genomic sequence can be inventive only if a specific and credible function has been disclosed. Further, according to AgrEvo, if the inventive step is predicated on an alleged surprising result, substantially everything within the scope of the claim should be capable of achieving the result. And the trend in the EPO may be that disclosure of most of a nucleic acid sequence may render a complete sequence obvious.

Business method patents

The rules of the JPO on novelty and inventive step closely mirror those of the USA:

Novelty/inventive step in JPO

- **Japanese Patent Law Sect. 29(1): novelty** (Sect. 29(1)). Any person who has made an invention which is industrially applicable may obtain a patent therefor, except in the case of the following inventions:
  (i) inventions that were publicly known in Japan or elsewhere prior to the filing of the patent application;
  (ii) inventions that were publicly worked in Japan or elsewhere prior to the filing of the patent application;
  (iii) inventions that were described in a distributed publication or made available to the public through electric telecommunication lines in Japan or elsewhere prior to the filing of the patent application.
- **Japanese Patent Law Sect. 29(2): inventive step** (Sect. 29(2)). Where an invention could easily have been made, prior to the filing of the patent application, by a person with ordinary skill in the art to which the invention pertains, on the basis of an invention or inventions referred to in any of the paragraphs of Subsection (1), a patent shall not be granted for such an invention notwithstanding Subsection (1).

Japanese patent law also requires that an inventive step appear in the invention, requiring both technical judgment and experience.

BUSINESS METHODS IN THE USA

As noted above, claim strategies to cover downstream products and for breadth include business method patents. Corporate interest in the protection of business methods afforded by the patent laws of the USA has been ignited in the wake of recent Federal Circuit case law and congressional legislation. The Federal Circuit's 1998 decision in *State Street Bank & Trust Co. v Signature Financial Group, Inc.*,[39] finding that business methods are patentable subject matter, and Congress's acknowledgment of this fact, have shown that patent protection of business methods has the potential of generating a tremendous amount of wealth. Just as one example, the controversial internet company Priceline.com was valued at nearly *ten billion* dollars in 2000; a significant part of the valuation being based on the more than 20 business method patents that the USPTO awarded to the company.[40]

It is unquestionable that business method patents are strategic corporate assets enabling companies to exert considerable influence in the marketplace. A company holding such a patent, especially on an emerging business method such as bioinformatics,[41] has the potential of wielding leverage over competitors (eg in the form of licences

and royalties) by virtue of the patent's quasi-monopoly power. Further, the company has the potential of acquiring greater market share and the heightened interest of institutional investors.

Samples of business method patents

Legislation was introduced in Congress on 3rd October, 2000, amending Section 100 of title 35 of the US Code to add the following broad definition of 'business method':

> The term 'business method' means –
> (1) a method of –
> (A) administering, managing, or otherwise operating an enterprise or organization, including a technique used in doing or conducting business; or
> (B) processing financial data;
> (2) any technique used in athletics, instruction, personal skills; and
> (3) any computer-assisted implementation of a method described in paragraph (1) or a technique described in paragraph (2).[42]

Business method defined

A business method patent is defined as a US utility patent whose subject matter is a method of doing or conducting business. Since a definition is often less effective than concrete examples. The following are some business methods to which the federal courts have been exposed over the years:

- A method of parking cars at a drive-in theatre that optimises view angles.[43]
- A business form with novel headings.[44]
- A method of accounting and cash registering to prevent fraud.[45]
- A vending process for use in selling stocks.[46]
- A method for implementing an interstate and national fire-fighting system.[47]

Although it is doubtful that one can point to the very first patented business method, the following are some historical examples of issued US patents to methods of doing business:

- **US Patent No. 63,889**, issued 16th April, 1867, claiming:

  A hotel register book with the margin of its leaves occupied by advertisements. . .

- **US Patent No. 395,781**, issued 1st January, 1889, claiming:

  The improvement in the art of compiling statistics, which consists in first, preparing a series of separate record cards, each card representing an individual or subject; second, applying to each card at predetermined intervals circuit-controlling index-points arranged, according to a fixed plan of distribution, to represent each item or characteristic of the individual or subject, and, third, applying said separate record-cards successively to circuit-controlling devices acted upon by the index-points to designate each statistical item represented by one or more of said index-points. . .

- **US Patent No. 853,852**, issued 14th May, 1907, claiming:

  [a] two part insurance policy consisting of a paper containing an insurance contract provided with suitably designated spaces for the signature of insurer and that of the insured combined with a postal card, both bearing a number or mark of identification, and the postal card bearing also printed reference to the contract paper and the beneficiary thereof. . .

The evolution of the business method patent will now be examined. Although would-be patentable inventions are required by statute to fall within either a process, machine, manufacture or

State Street

composition of matter,[48] it is often the federal courts that ultimately decide what subject matter is, in fact, patentable. Until quite recently, the great weight of judicial authority has consistently held that methods of doing business were mere abstract ideas and, therefore, unworthy of patent protection.

The Second Circuit took the lead in scuttling the patentability of business methods in its landmark 1908 decision *Hotel Security Checking Co. v Lorraine Co.*[49] In that case, the invention involved a bookkeeping system for cash-registering and account-checking designed to prevent fraud by waiters. In holding the method unpatentable, the court adamantly stated: 'A system for transacting business disconnected from the means for carrying out the system is not . . . an art [process].'[50]

Evolution

Other courts followed suit. For example, in *Ex parte Murray*,[51] the Board of Patent Appeals and Interferences held that an accounting method:

> [R]equiring no more than entering, sorting, debiting and totaling of expenditures as necessary preliminary steps to issuing an expense analysis statement, is, on its face, a vivid example of the type of 'method of doing business' . . . as outside the protection of the patent statutes. . .[52]

The reasoning behind what has been called the 'business method exception' to patentability included the requirement that inventions be reduced to tangible form, eg tangible things and procedures. Consequently, mere ideas were unpatentable. Practitioners have also noted that, historically:

> [B]usiness methods as bookkeeping procedures and investment management strategies were difficult to characterize as innovations in the technological or 'useful' arts entitled to patent protection. Most of these methods were carried out by hand with pen and paper and did not appear to involve any technological art. . .[53]

Recently, the 'business method exception' was eliminated by the Federal Circuit in *State Street v Signature Financial*,[54] one of the court's most heralded and far-reaching decisions to date. The patent-at-issue was owned by Signature Financial and entitled 'Data Processing System for Hub and Spoke Financial Services Configuration.' The patent was directed to a data-processing system for implementing an investment structure by which mutual funds (the 'spokes') pooled assets in an investment vehicle (the 'hub') organised as a partnership. Using the system, one could easily allocate daily income, expenses and net realized gain or loss among the mutual funds. Claim 1 was written in means-plus-function form and recited the following:

1. A data processing system for managing a financial services configuration of a portfolio established as a partnership, each partner being one of a plurality of funds, comprising:
   (a) computer processor means for processing data;
   (b) storage means for storing data on a storage medium;
   (c) first means for initializing the storage medium;
   (d) second means for processing data regarding assets in the portfolio and each of the funds from a previous day and data regarding increases or decreases in each of the funds, assets and for allocating the percentage share that each fund holds in the portfolio;
   (e) third means for processing data regarding daily incremental income, expenses, and net realized gain or loss for the portfolio and for allocating such data among each fund;
   (f) fourth means for processing

> data regarding daily net unrealized gain or loss for the portfolio and for allocating such data among each fund; and
>
> (g) fifth means for processing data regarding aggregate year-end income, expenses, and capital gain or loss for the portfolio and each of the funds.

The district court held that the claims involved business plans and systems (ie methods of doing business) and were, therefore, unpatentable subject matter *per se*. The Federal Circuit disagreed, holding that business methods were, indeed, patentable subject matter if the result was a useful, tangible or concrete invention.

The Federal Circuit began its analysis by noting that since the claims were in means-plus-function format, and when claim 1 was properly construed in accordance to Section 112, paragraph 6, the invention was directed to a machine. Further, since each claim component was recited in means-plus-function form, it was to be inclusive of the 'equivalents' of the structures disclosed in the written description. Claim 1, properly construed, therefore, was a machine and, for purposes of Section 101, proper statutory subject matter.[55]

The court did not end there. It expressly characterised the 'business method exception' as 'ill-conceived' and rendered irrelevant by Section 103.[56] Tellingly, the court stated that:

> Since the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.[57]

The Federal Circuit's decision in *State Street* is important for a number of reasons. First, it gives a hint to the practitioner of how to avoid any residual 'business method' dilemmas. By reciting the business method in proper means-plus-function format, ie one in which the invention is defined by function rather than by structure and inclusive of the equivalents in the specification, a machine may be claimed that would naturally fall within Section 101.

Second, the court considered business methods equivalent to other conventional methods or processes. Consequently, business methods are now to be treated no differently from any other method for purposes of patentability. Under this rubric, Section 102, 103 and 112 analyses should be the same when business method inventions are prosecuted (*see infra*).

Third, and related to the first point above, the decision indicates that even if the patent did not include any method claims, but included, instead, claims directed to 'means for' performing the business method, the patent would still be construed as a business method patent. Of course, the claimed invention, according to the Federal Circuit, would be characterised as a machine and would bypass the Section 101 inquiry.

Most importantly, the court promulgated a new standard for patentable subject matter. As long as the method or process had a practical utility in producing a 'useful, concrete, and tangible result,' the requirements of Section 101 would be satisfied.[58] The consequences of such a standard are staggering, and renders prophetic the oft-quoted statement by the Supreme Court that patentable subject matter is 'anything under the sun that is made by man.'[59]

TRILATERAL COOPERATION

Trilateral cooperation

With the understanding that globalisation is in the best interest of the economies of the USA, Europe and Japan, 'harmonisation' between the three patent offices has been a buzz-word for over the past 20 years. An approach to a more unified patenting system, however, has been elusive. Many of the obstacles to such a unified, global system are based on a lack of awareness of not only the rules underlying the examination procedure of the three patent offices, but also of an unfamiliarity of the reasons for these rules.

The Trilateral Cooperation initiative best outlines the USPTO, EPO and JPO rules in action, and the reasons behind them. The conference is held annually to exchange insight and cultural reasoning among the participants. According to the USPTO:

> The advantage of such a system for the users of the patent system would be reduction of costs, improvement of granted patents' quality, improvement of patent information dissemination reduction of processing time in the patent granting procedure.[60]

More importantly, however, the trilateral cooperation initiative places the public on notice. Specifically, corporations, institutions and individual inventors, and the patent lawyers representing them need to know how to navigate the systems in each of the three patent offices most advantageously.

With respect to biotechnology, two projects are particularly relevant: Trilateral Project B3b: Comparative study on biotechnology patent practices (patentability of DNA fragments) and Trilateral Project WM4: Comparative studies in new technologies (protein 3-dimensional structure related claims). These two projects are summarised below.

Trilateral Project B3b[61]

Project B3b

Six hypothetical cases were presented to the USPTO, EPO and JPO for comments on patentability. These claims, and the comments accompanying them, were as follows.

Case A: A polynucleotide consisting of the nucleotide sequence of SEQ ID No. 1

The claimed polynucleotide is 500 base pairs (bp) cDNA obtained from human liver cDNA library. The polynucleotide can be used as a probe in one of the steps to obtain the full-length DNA, though there is no description of the function or biological activity of the DNA and its corresponding protein.

There is no known nucleotide sequence with high similarity to that of SEQ ID No. 1.

Case B: A polynucleotide consisting of the nucleotide sequence of SEQ ID No. 2

The claimed polynucleotide is 500 bp cDNA obtained from human liver cDNA library and assumed to be part of a structural gene encoding human protein X as a result of similarity search. (The polynucleotide demonstrated 95 per cent homology to part of a structural gene encoding rat protein X. The deduced amino acid sequence also showed 95 per cent homology to amino acid sequence of rat protein X.)

The polynucleotide can be used as a probe in one of the steps to obtain the full-length DNA encoding human protein X.

The size of the full-length DNA encoding rat protein X is 2400 bp and the DNA sequence encoding rat protein X was known.

Case C: A polynucleotide consisting of the nucleotide sequence of SEQ ID No. 3

The claimed polynucleotide is 500 bp cDNA obtained from human liver cDNA library. As the amino acid sequence deduced from the nucleotide sequence of SEQ ID No. 3 has a potential site of glycosylation, the polynucleotide is assumed to be part of a structural gene encoding a glycoprotein.

The polynucleotide can be used as a probe in one of the steps to obtain the full-length DNA.

There is no known nucleotide sequence with high similarity to that of SEQ ID No. 3.

Case D: A polynucleotide consisting of the nucleotide sequence of SEQ ID No. 4

The polynucleotide is 500 bp long cDNA whose corresponding mRNA is expressed only in the hepatocyte of the patients with disease Y. Therefore, the polynucleotide can be used as a probe to diagnose disease Y.

There is no known DNA that is unique

in the patients with disease Y or high similar to that of SEQ ID No. 4.

Case E: A polynucleotide comprising the nucleotide sequence of SEQ ID No. 4
Case E differs from Case D only in terms of the expression of 'comprising' and 'consisting of' used for the claims respectively.

Case F: A structural gene comprising the nucleotide sequence of SEQ ID No. 2
Case F differs from Case B in terms of the expression of the preamble language and the transition phrase.[62]

According to the comparative study, all three patent offices indicated that Cases A, B, C and F are not patentable. The three offices believed, however, that Case D was patentable. The USPTO based its reasoning for unpatentability on lack of utility and enablement. The EPO and the JPO, by contrast, noted that the cases failed the requirements for non-obviousness and inventive step.[63] The three offices made the following conclusions:

Project WM4

- A mere DNA fragment without indication of a function or specific asserted utility is not a patentable invention.
- A DNA fragment, of which specific utility, eg use as a probe to diagnose a specific disease, is disclosed, is a patentable invention as long as there is no other reasons for rejection.
- A DNA fragment showing no unexpected effect, obtained by conventional method, which is assumed to be part of a certain structural gene based on its high homology with a known DNA encoding protein with a known function, is not a patentable invention (EPO, JPO).
- The above-mentioned DNA fragment is unpatentable if the specification fails to indicate an asserted utility (USPTO).
- The mere fact that DNA fragments are derived from the same source is not sufficient to meet the requirement for unity of invention.
- All nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, without indication of function or specific, substantial and credible utility, do not satisfy industrial applicability, enablement or written description requirements.
- Isolated and purified nucleic acid molecule-related inventions, including full-length cDNAs and SNPs, of which function or specific, substantial and credible utility is disclosed, which satisfy industrial applicability, enablement, definiteness and written description requirements would be patentable as long as there is no prior art (novelty and inventive step) or other reasons for rejection (such as, where appropriate, best mode [US] or ethical grounds [EPC/JP]).[64]

Trilateral Project WM4[65]

Eight cases were presented to the USPTO, EPO and JPO on technology related to 3D chemical structures.

***Case 1: 3D structural data of a protein* per se**

- Claim 1: A computer model of protein P generated with the atomic coordinates listed in Figure 1 of Ref. 65.
- Claim 2: A data array comprising the atomic coordinates of protein P as set forth in Figure 1 (of Ref. 65) which, when acted upon by a protein modeling algorithm, yields a representation of the 3D structure of protein P.

Background:

- The specification asserts that protein P is a novel protein.

- The description gives experimental data and explains that the protein, when active, lowers blood pressure.

- Protein modelling algorithms are well known in the art.

- The description also gives the atomic coordinates of protein P, and asserts these coordinates would be useful in *in silico* (computer-assisted) screening methods.

Prior art:

- A search of the prior art did not identify any references that teach or suggest protein P.

Case 2: Computer-readable storage medium encoded with structural data of a protein

- Claim 1: A computer-readable storage medium encoded with the atomic coordinates of protein P as shown in Figure 1 of Ref. 65.

Background and prior art: same as in Case 1.

Case 3: Protein defined by its tertiary structure

- Claim: An isolated and purified protein having the structure defined by the structural coordinates as shown in Figure 1 of Ref. 65.

Background:

- The description sets forth the 3D structure of protein P, including the coordinates of the amino acid side chains, the source organism for protein P and the molecular weight of protein P.

- The description gives experimental data and explains that administering protein P lowers blood pressure.

- The structural coordinates were derived from a solution phase protein by nuclear magnetic resonance (NMR) at 0.2 nm resolution.

Prior art:

- A search of the prior art did not identify any references that teach or suggest the 3D structure of protein P.

- The prior art teaches a protein from the same source organism having the same specific function and approximately the same molecular weight.

Case 4: Crystals of known proteins

- Claim: A crystalline form of protein P having unit cell dimensions of $a = 4.0$ nm, $b = 7.8$ nm and $c = 11.0$ nm.

Background:

- A nucleotide sequence encoding the amino acid sequence of protein P was known in the art.

- The description explains that administering protein P was previously known to result in lowering blood pressure.

- The inventors assert they have newly produced a stable crystalline form of protein P.

- Protein P in crystalline form is inactive.

- The description gives experimental data with explanations of how to make the crystals.

- Common prior art methods used in protein P crystallisation were unsuccessful, and there was clearly a

technical difficulty in producing the claimed crystalline form of protein P.

Prior art:

- There was no prior art reference teaching or suggesting a crystal of protein P or related proteins.
- There was no prior art reference concerning the crystallisation method of protein P.

Case 5: Binding pockets and protein domains

- Claim 1: An isolated and purified molecule comprising a binding pocket of protein P defined by the structural coordinates of amino acid residues 223, 224, 227, 295, 343, 366, 370, 378 and 384 according to Figure 1 of Ref. 65.
- Claim 2: An isolated and purified polypeptide consisting of a portion of protein P starting at one of amino acids 214 to 218 and ending at one of amino acids 394 to 401 of protein P as set forth in SEQ ID No. 1.

Background:

- Protein P is a previously known protein whose amino acid sequence was also previously known.
- The description explains that administering protein P was previously known to result in lowering blood pressure.
- The inventors assert they have newly discovered that the active residues in the binding pocket of protein P consist of amino acids 223, 224, 227, 295, 343, 366, 370, 378 and 384.
- The description teaches that the possible peptides that begin with any amino acid from position 214 to 218 and end with any amino acid from position 394 to 401 of SEQ ID No. 1 are protein domains that are able to fold into an active binding pocket of protein P. This ability was confirmed by X-ray diffraction data.
- The description also provides evidence that the above domain alone shows a significantly higher signalling activity compared with the whole protein P when activated by a natural ligand of protein P.

Prior art:

- Prior art suggesting the position of the binding pocket of protein P was not found.
- Prior art suggesting a protein structure domain containing said binding pocket was also not found.

Case 6: In silico screening methods directed to a specific protein (1)

- Claim: A method of identifying compounds that can bind to protein P, comprising the steps of: (1) applying a 3D molecular modelling algorithm to the atomic coordinates of protein P shown in Figure 1 of Ref. 65 to determine the spatial coordinates of the binding pocket of protein P; and (2) electronically screening the stored spatial coordinates of a set of candidate compounds against the spatial coordinates of the protein P binding pocket to identify compounds that can bind to protein P.

Background:

- Protein P is a previously known protein whose amino acid sequence was also previously known.
- The description explains that the activity of protein P was previously known to result in lowering blood pressure.

- The description gives the atomic coordinates of protein P (raw data of the protein itself without any ligands bound to it) but does not describe the position of its binding pocket.

- Instead, the specification gives general information on programs that predict the binding pocket of proteins (which often give a relatively large number of amino acids related to the binding) and general information on commonly used *in silico* screening programs.

- Methods of peptide modelling and binding using rational drug design are well known in the art.

- There was clearly a technical difficulty in obtaining the claimed atomic coordinates of protein P.

- The specification speculates that by using the binding pocket prediction program and *in silico* screening program, the person skilled in the art can identify compounds binding to said protein.

- The description gives no working examples of identifying compounds using the atomic coordinates of protein P.

Prior art:

- No prior art suggesting the 3D coordinates of protein P was found.

- The prior art teaches computer programs that predict the binding pocket of proteins.

- Several *in silico* screening programs using the predicted binding pocket of proteins are also previously known.

Case 7: In silico screening methods directed to a specific protein (2)

- Claim 1: A method of identifying compounds that can bind to protein P by comparing the 3D structure of candidate compounds with the 3D molecular model shown in Figure 5 of Ref. 65 which comprises the following steps:

(1) . . .

(2) . . .

(..) . . .

(*n*) . . .

The 3D molecular model of Figure 5 presents the positions of heteroatoms in the amino acids constituting the binding pocket of protein P (ie amino acids 223, 224, 227, 295, 343, 366, 370, 378 and 384) wherein said heteroatoms can form hydrogen bonds with hydrogen bonding functional groups in a candidate compound.

Steps (1) to (*n*) describe a data processing method in which (a) the coordinate data of the 3D molecular model of Figure 5 (of Ref. 65) is input in a data structure such that the interatomic distances between the atoms of protein P are easily retrieved, and (b) the distances between hydrogen-bonding heteroatoms of different candidate compounds and the heteroatoms that form the binding pocket in the 3D molecular model are compared, thereby allowing the identification of those candidate compounds which would theoretically form the most stable complexes with the 3D molecular model binding pocket of protein P, based on optimal hydrogen bonding between the two structures.

- Claim 2: A compound identified by the method of claim 1.

- Claim 3: A database encoded with data comprising names and structures of compounds identified by the method of claim 1.

Background:

- Protein P is a previously known protein whose amino acid sequence was also previously known.
- The description explains that the activity of protein P was previously known to result in lowering blood pressure.
- The description gives the atomic coordinates of protein P as a co-crystal with its natural ligand, and gives a logical explanation that the active residues in the binding pocket of protein P consists of amino acids 223, 224, 227, 295, 343, 366, 370, 378 and 384.
- The description explains how the 3D molecular model of Figure 5 includes the 3D structure of the binding pocket of protein P.
- The description gives working examples of the claimed method in which a number of compounds are identified.
- The description also shows experimental data of the actual binding affinities of the compounds identified. According to the data shown, the person skilled in the art can understand that the claimed method can actually identify a number of compounds which bind strongly enough to protein P so that some biological effect can be expected.

Prior art:

- No prior art suggesting the 3D coordinates of protein P was found.
- The prior art teaches *in silico* screening programs that compare the 3D structure of candidate compounds with the 3D molecular model of the binding pocket of a protein of interest.
- The method of storing coordinate data to optimise the interatomic distance information is taught by the prior art.

Case 8: Pharmacophores and pharmacophore defined compounds (pharmacophores defined by the distance between atom-groups)

- Claim 1: A pharmacophore having a spatial arrangement of atoms within a molecule defined by formula 1 TYPE = PICT; ALT = Pharmacophore of Formula 1 having three atoms, namely A, B and C, wherein the distance between A and B is 1.59 ± 0.50 nm, the distance between B and C is 1.33 ± 0.25 nm, and the distance between A and C is 0.95 ± 0.25 nm in which A and B both represent an electron donor atom, C represents a carbon atom that is part of a hydrophobic group, and the distances represent the distances between the centres of the respective atoms.
- Claim 2: An isolated compound or its salt defined by the pharmacophore in claim 1.

Background:

- A pharmacophore is a description of a generalised concept of molecular features in terms of information on spatial arrangement of chemical elements (eg hydrophobic groups, charged/ionisable groups, hydrogen bond donors/acceptors, and substructures) that are considered to be responsible for a desired biological activity.
- Protein P is a previously known protein whose amino acid sequence was also previously known.
- The description explains that the activity of protein P was previously known to result in lowering blood pressure.

- A search of the prior art did not identify any references that teach or suggest the 3D structure of protein P.
- The description teaches that the pharmacophore shown in formula 1 was evaluated from the 3D structure of the ligand binding pocket of protein P.
- The description also teaches that the structure of the ligand binding pocket of protein P was estimated using conventional methods.
- The description also describes that a novel ligand was designed based on the pharmacophore, and shows experimental results that the ligand binds to the protein with relatively high affinity.

Prior art:

- A document showing an agonist of protein P was found.[66]

Tables 2–4 show howTrilateral Project WM4 summarised the findings of the three patent offices.

The offices also noted that the claims for:

- computer models of protein;
- data array comprising atomic coordinates of protein;
- computer-readable storage medium encoded with atomic coordinates of protein;
- database encoded with data comprising names and structures of compounds; and
- pharmacophore

are *not* patent eligible subject matter or statutory inventions.

In cases where no references teach or suggest the 3D structure of protein but there is enough reason to expect that the claimed protein would be *prima facie* identical with the protein of the prior art, the claim for a protein having the structure defined by the structural coordinates does *not* comply with the requirements of novelty.

A crystalline form of a protein meets all the requirements of patent eligible subject matter, statutory invention, industrial applicability (application), utility, enablement, support, clarity, written description, novelty, inventive step and

Table 2: Summary of answers – EPO[67]

Case	Claim	Patent eligible subject matter	Industrial applicability	Clarity/ Support	Sufficiency	Novelty and inventive step
1	1	N	N/A	N/A	N/A	N/A
	2	N	N/A	N/A	N/A	N/A
2	1	N	N/A	N/A	N/A	N/A
3	1	Y	Y	Y	Y	N
4	1	Y	Y	Y	Y	Y
5	1	Y	Y	N	N	N
	2	Y	Y	Y	Y	Y
6	1	Y	Y	Y	N	Y
7	1	Y	Y	Y	Y	Y
	2	Y	Y	N	N	M
	3	N	N/A	N/A	N/A	N/A
8	1	N	N/A	N/A	N/A	N/A
	2	Y	Y	N	N	N

Y = Yes, N = No, N/A = not addressed and M = Maybe.

Table 3: Summary of answers – JPO[67]

Case	Claim	Statutory invention	Industrial applicability	Clarity	Enablement	Novelty and inventive step
1	1	N	N/A	N/A	N/A	N/A
	2	N	N/A	N/A	N/A	N/A
2	1	N	N/A	N/A	N/A	N/A
3	1	Y	Y	Y	Y	N
4	1	Y	Y	Y	Y	Y
5	1	Y	Y	N	N	N
	2	Y	Y	Y	Y	Y
6	1	N	Y	N/A	N/A	N/A(N)
7	1	Y	Y	Y	Y	N
	2	Y	Y	N	N	N/A
	3	N	N/A	N	N	N/A
8	1	N	N	N	N/A	N/A
	2	Y	Y	N	N	N

To the general scope of the claim.
Y = Yes, N = No, N/A = not addressed and M = Maybe.

Table 4: Summary of answers – USPTO[67]

Case	Claim	Patent eligible subject matter	Utility	Written description	Enablement	Novelty and inventive step
1	1	N	M	Y	N	N/A
	2	N	M	Y	N	N/A
2	1	N	M	Y	N	N
3	1	Y	Y	Y	Y	N
4	1	Y	Y	Y	M	M
5	1	Y	Y	N	N	N
	2	Y	Y	Y	Y	Y
6	1	Y	M	Y	N	N
7	1	Y	M	Y	M	N
	2	Y	M	N	N	M
	3	N	N/A	N/A	N/A	N/A
8	1	N	N/A	N/A	N/A	N/A
	2	Y	M	N	N	M

Y = Yes, N = No, N/A = not addressed and M = Maybe.

non-obviousness since a protein is composition of matter of patentable subject or statutory invention, if:

- it is well established in the art that the crystalline form of the protein has utility or industrial applicability, and
- the specification teaches how to make the claimed crystals, and
- one skilled in the art could use the claimed protein crystal without undue experimentation, and
- characterisation of the crystal structure is provided in the claim (eg by specifying the cell unit dimensions), and
- there was no prior art reference teaching or suggesting a crystal of the protein or related proteins, and
- there was no particular guidance in the art as to how to crystallise the protein.

In cases where a protein is previously known, the claim for an isolated and purified molecule comprising a binding

pocket of protein defined by the structural coordinates does *not* comply with all of the requirements of enablement, support, clarity, written description, novelty, inventive step and non-obviousness.

An isolated and purified polypeptide consisting of a portion of a protein with signalling activity meets all the requirements of patent eligible subject matter, statutory invention, industrial applicability (application), utility, enablement, support, clarity, written description, novelty, inventive step and non-obviousness since:

- it is limited to a fragment of the protein that contains the binding pocket and was shown in the specification to retain binding activity and the signalling activity of the protein, and
- the prior art does not teach any polypeptide which consists of the claimed specific part of the protein, or methods to specify parts of the polypeptide, and
- it shows a significantly higher signalling activity compared with the whole protein.

The claim for compounds in general identified by *in silico* screening methods does *not* comply with enablement, support, clarity and/or written description.

In a case where the description gives no working examples of identifying compounds using the atomic coordinates of the protein, and the difference between the prior art and the claimed invention as a whole is limited to atomic coordinates stored on or employed by a machine, the claim for *in silico* screening method does not comply with one or more of the requirements of patent eligible subject matter, statutory invention, industrial applicability (application), utility, enablement, support, clarity, written description, novelty, inventive step and/or non-obviousness.

The claim for compounds or their salts in general defined by a pharmacophore does *not* comply with one or more of the requirements of enablement, support, clarity and/or written description because:

- it would require a trial and error effort beyond what is expected of a person having ordinary skill in the art to envisage a ligand structure other than the one described concretely in the examples, and make such compounds, and
- the pharmacophore, which is an abstract concept, does not define a compound.[68]

Final thoughts

CONCLUSION

Corporate and academic applicants must be aware that optimising the scope of patent protection requires patents from the USPTO, the EPO and the JPO. As these offices control global IP, patent counsel, in turn, must have expertise in all three systems to efficiently (and profitably) advocate their clients' interests.

References and notes

1. Press Release, United States Patent & Trademark Office (29th November, 2002) (URL: http://www.USPTO.gov/web/offices/com/speeches/02-70.htm).
2. *Brenner v Manson*, 383 US 519, 536, 148 USPQ 689, 696 (1966).
3. 2002 W.L. 31497300 (Fed. Cir. Nov. 8, 2002).
4. *Id*. at *1 (internal citations omitted).
5. OJ EPO June 2002, pp. 275–343.
6. *See* Japanese Patent Office website, Requirements for Patentability (URL: http://www.deux.JPO.go.jp/cgi/search.cgi?query=method+of+medical+treatment&lang=en&root=short/ last visited 11th March, 2003).
7. *See, generally,* Martin, T. (2000), 'Patentability of methods of medical treatment: A comparative study', *J. Pat. Trademark Off. Soc.*, Vol. 82, p. 381.
8. *See* Section 29(1) of the Japanese Patent Law. *See also*, Part II, Chap. 1(2.1) on industrial inapplicability.
9. *Supra*, note 6 at 397.

10. *Id*.
11. *See In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).
12. *See Wands*, 858 F.2d at 737.
13. *See* Art. 83 EPC.
14. *See* 66 F.R. 1099.
15. *Id*. at 1104–05 (internal citations omitted).
16. 568 F.2d 1349 (CCPA 1978).
17. *Id*. at 1351–52.
18. *See Vas-Cath, Inc. v Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991).
19. *Fiers v Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1983).
20. *See id*., 984 F.2d at 1169–71.
21. *See id.; see also Regents of the Univ. of Cal. v Eli Lilly & Co*., 119 F.3d 1559 (Fed. Cir. 1997).
22. *See In re Borkowski*, 422 F.2d 904 (CCPA 1970).
23. *See id*. at 909. ('If the scope of the subject matter embraced by a claim is clear, *and* if the applicant has not otherwise indicated that he intends that claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention.')
24. *See Solomon v Kimberly-Clark Corporation*, 216 F.3d 1372, 1379 (Fed. Cir. 2000). ('As has been noted in the context of definiteness, the inquiry under section 112, paragraph 2, now focuses on whether the claims, as interpreted in view of the written description, adequately perform their function of notifying the public of the patentee's right to exclude.')
25. *See Atmel Corporation v Information Storage Devices, Inc.*, 198 F.3d 1374, 1378 (Fed. Cir. 1999). (Noting that 'as a general matter, it is well-established that the determination whether a claim is invalid as indefinite' is dependent upon whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification.)
26. *See In re Cohn*, 438 F.2d 989 (CCPA 1971).
27. See the Decision of the Technical Board of Appeal T409/91.
28. See the Decision of the Technical Board of Appeal T435/91.
29. *See*, Japanese Patent Office website, Clarity and Enablement (URL: http://www.deux.JPO.go.jp/cgi/search.cgi?query=enablement&lang=en&root=short/ last visited 11th March, 2003).
30. *Id*.
31. *See In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990); *W. L. Gore & Assoc. v Garlock, Inc.*, 721 F.2d 1540, 1544 (Fed. Cir. 1983).
32. *See Constant v Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1575 (Fed. Cir. 1988).
33. See Lindemann Maschinefabrik v American Hoist & Derrick Co., 730 F.2d 1452, 1548 (Fed. Cir. 1984).
34. *See, eg, ACS Hosp. Sys., Inc. v Montefiore Hosp.*, 732 F.2d 1572, 1577 (Fed. Cir 1984); *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988).
35. 383 US 1 (1966).
36. *See id*.
37. *See id*.
38. *In re Baird*, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).
39. 149 F.3d 1368 (Fed. Cir. 1998).
40. *See* Guffey, L. J. (2000), *33 Maryland Bar J*., Vol. 25 (2000).
41. See, eg, US Patent No. 6,185,561 (relating to computer systems and more particularly to computer systems for mining information about gene expression levels. Claim 1 reads: 'A computer based method for mining a plurality of experiment information for a pattern, said method comprising: collecting expression levels of a plurality of genes in said plurality of experiments, wherein said expression levels are measured using nucleic acid microarray chips; collecting a plurality of attributes from experiments and designs of said chips; defining at least one of a plurality of groupings for said experiments to be mined; selecting based upon said at least one of a plurality of groupings, information about said plurality of experiments to be mined, forming a plurality of resulting information, said plurality of resulting information including at least a resulting gene set and said expression levels for genes of said resulting gene set; and formatting said plurality of resulting information for viewing by a user.')
42. H.R. 5364, 106th Congress (2000).
43. *See Loew's Drive-In Theatres, Inc., v Park-In Theatres, Inc.* 174 F.2d 547 (1st Cir. 1949).
44. *See U.S. Credit System Co. v American Indemnity Co*., 59 F. 139 (2nd Cir 1893).
45. *See Hotel Checking Co. v Lorraine Co*., 160 F. 467 (2nd Cir. 1908).
46. *See In re Wait*, 24 USPQ 88 (CCPA 1934).
47. *See In re Patton*, 127 F.2d 324 (CCPA 1942).
48. *See* 35 USC §101 ('Whoever invents or discovers any new or 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.').
49. 160 F. 467 (2nd Cir. 1908).
50. *Id*. at 469.

51. 9 USPQ 2nd 1819 (PTO Bd. Pat. App. & Int'f 1988).
52. *Id*. at 1820.
53. Scheinfeld, R. C. and Bagley, P. H. (1998), 'State Street: ''Virtually anything is patentable'' ', *New York Law J*., 23rd September, p. 3.
54. 149 F.3d 1368 (Fed. Cir. 1998).
55. *State Street*, at 1371–72.
56. *Id*. at 1375.
57. *Id*.
58. *See id*.
59. *Diamond v Chakrabarty*, 447 US 303, 309 (1980).
60. United States Patent & Trademark Office (URL: http://www.USPTO.gov/web/tws/gen-1.htm) (last visited 11th March, 2003).
61. United States Patent & Trademark Office (URL: http://www.USPTO.gov/web/tws/sr-3-b3b-ad.htm last visited 11th March, 2003).
62. *See id*.
63. *See id*.
64. *See id*.
65. United States Patent & Trademark Office (URL: http://www.USPTO.gov/web/tws/wm4/wm4_3d_rE.P.O.rt.htm last visited 13th January, 2003).
66. *See id*.
67. *Id*.
68. *See id*.