INTERNATIONAL FILING STRATEGIES AND COST MANAGEMENT: MATERIAL PATENTABILITY REQUIREMENTS

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Despite global harmonization efforts, significant differences remain in regard to the material requirements for obtaining a patent, including patent eligible subject-matter, novelty, inventive step, written description/enablement requirements and clarity (definitiveness). Based on these differences, the possibility to obtain the broadest possible patent protection in different jurisdictions may be significantly affected by the disclosure provided in the first filing, which is the basis for prosecution in international jurisdictions chosen at a later stage

Often, when drafting a patent application for the first filing, the specific opportunities and limitations of a given applicant's own "key jurisdiction" determine what is (and what is not) originally disclosed. However, in order to achieve the best results in as many jurisdictions as possible, it may be advantageous to (also) consider, already at this first stage, specific requirements in regard to material patentability for key jurisdictions in which the first filing will likely be prosecuted. As a rule of thumb, whenever possible, the strictest requirements in the most "difficult" jurisdictions should be considered when several options exist how to draft the first filing.

For example, while data and comparative experiments can usually be easily provided at a later stage in proceedings before the USPTO, this may not be (as) easy in other jurisdictions, for example in Europe and in China. Therefore, in particular in the "*unpredictable arts*" (Chemistry, Life Sciences) which usually require experimental data to support enablement and inventive step, it is advantageous, and in some cases even mandatory, to provide as many data as possible, including comparative and conceptual data, at the earliest possible stage. In another example, "gene patents" are currently difficult to obtain in the US, and applicants may be discouraged from filing claims directed at gene sequences. However, the same is not true for other jurisdictions, for

example Europe and Japan. Therefore it may make sense to provide disclosure for broad claims (that may not be obtainable in the US) in a US-based first filing, if the respective application is to be filed in other jurisdictions as well. In a last example, functional features are treated quite differently in different jurisdictions and are typically more easily included in claims in Europe, Canada, Japan and the US (taking the “means plus function” limitation into account), while claims typically require structural limitations for the jurisdictions of China and Korea. Therefore, it is advisable to have both broad functional features and “structural” fallback positions in the first filing to have a reasonable chance to obtain broad patent protection in different jurisdictions.

A schematic summary of the material patentability requirements in key IP jurisdictions (US, CA, EP, JP, CN, KR) is provided in the attached Overview Tables. All information has been provided by national council in the respective jurisdictions, but, naturally, can only be a brief and schematic summary of the most important principles applicable in the respective jurisdiction. Needless to say that these schematic summaries, as well as all conclusions provided in this article, cannot substitute for legal advice applicable to specific cases in a specific jurisdiction. Furthermore, although believed to be correct, any information or conclusion provided may be incomplete and also may be subject to changes. As an example, until recently, it was not possible to provide post-filed experimental data in China. This situation has only changed recently (effective April 1, 2017) in that the patent examination guidelines now state that data may be submitted after the date of filing (provided that the technical effect supported by such post-filed data is obtainable from the disclosure of the patent application).

As is apparent from the examples provided above and the schematic overview provided in the enclosed Overview Tables, the various material patentability requirements vary significantly across different jurisdictions. This highlights the need or at least the advantage of considering specific requirements in different jurisdictions, in regard to all material patentability requirements, as early as possible, ideally when drafting the first filing. Properly taking into account these differences may be a significant cost-saving measure, as duplication of costs across jurisdictions is avoided or minimized and broader protection is achieved, ideally eliminating the need to file costly follow-up or divisional applications in different jurisdictions.

Material Patentability Requirement	US	CA	EP	JP	CN	KR
Excluded categories for patentability (exceptions to patentability)	Judicial exceptions - laws of nature - natural phenomena - abstract ideas	Statutory exceptions: - mere scientific principles and abstract theorems (business methods may be patentable on a case-by-case basis) Judicial exceptions: - higher life forms (including plants, seeds, animals, totipotent stem cells) - methods of medical treatment (but "use of x for treatment of y" is patentable)	Statutory exceptions [Art. 52, 53 EPC]: - against "ordre public" - plant or animal *varieties* and "essentially biological" processes - **methods** of medical treatment / surgery / invasive diagnostics - "non-technical" (computer imple-mented "as such"; business methods) - aesthetic creations	Statutory exceptions [Art. 32 of Japanese Patent Law (JPL)]: - against public order, morality or "public health" Examples: law of nature as such; mere discoveries; non-technical idea; etc. (Business methods are patentable provided that hardware resources to achieve the objective of the method is recited in a claim)	Article 25: - Scientific Discoveries - Rules and Methods for Mental Activities - Methods for Diagnosis or for Treatment of Diseases - Animal and Plant Varieties - Methods of Nuclear Transformation and Substances so Obtained Article 5.2: - use of genetic resources, not consistent with the provisions of the laws and administrative regulations.	Statutory exceptions [Art. 32] **(Unpatentable Inventions)** Inventions that violate public order or sound morals, or are likely to harm public health are not patentable. [Examination guidelines of KIPO] List of industrially **in**applicable inventions methods for treatment of the human body by surgery or therapy or diagnostic methods practiced on the human body

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Limitations on Pharma/Biotech inventions	Biotechnology and pharma inventions are patentable, in principle (unless directed at "laws of nature" or "natural phenomena" without inventive surplus); case law is developing in wake of “Myriad” and "Mayo" decisions	Methods of treatment cannot be patented but methods of diagnosis can. “Use” claims are patentable, in the format of “Use of X to treat disease Y,” however, caution must be used with dosage regimes and diagnostic claims that merely correlate natural phenomena with one another. "Promise doctrine" that was seen as problematic is being abandoned. Plants and animals cannot be claimed, but cells can be. It has been held that if a plant or animal contains a single patented cell, then the plant or animal would be found to infringe the cell claim.	*Methods* of treatment cannot be patented, but: first or second medical use claims ("purpose limited") allowable; "Swiss”-type-claims no longer allowable; Diagnostics methods only patentable if not invasive (devices are no problem) biotechnology inventions generally patentable (with narrow exceptions such as prohibition of use of embryos or claiming animal or plant varieties) see EU “Biotechnology Directive” (98/44/EC)	Methods of surgery, therapy or diagnosis of human body non-patentable (lack of industrial applicability) (Art. 29, Par.1, body JPL); Methods applied to non-human animal are patentable. Medical use can be pursued by pharmaceutical composition claim [Swiss-type claims allowable but enforceability is questionable (can be construed as covering only a process for manufacturing the drug)] Diagnostic methods are non-patentable, but can be pursued by rewriting the claim as, for example, detecting method, diagnostic assisting etc. Biotechnology inventions generally patentable provided that not against public order	Methods of diagnosis and treatment cannot be patented, but: "Swiss”-type-claims are allowable; Diagnosis and treatment methods only patentable if not invasive (devices and substances are no problem); biotechnology inventions generally patentable except for embryonic stem cells and the human body, at the various stages of its formation and devel-opment, including a germ cell, an sperm, an embryo and an entire human body	[see "Excluded Categories" above]

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<u>Novelty:</u> **Scope of novelty assessment**	"absolute" (oral, written, abroad)	"absolute" (oral, written, abroad) Requires both disclosure and enablement, assessed in that order Smallest unit: day	Art. 54 EPC: "absolute" [oral (explicit), written, abroad] smallest unit: day	"absolute" [oral (implicit), written, abroad] smallest unit: HH:MM	"absolute" [oral (implicit), written, abroad] smallest unit: day	"absolute" [oral (implicit), written, abroad] smallest unit: HH:MM
<u>Novelty:</u> **Relevance of "post-published" prior art (i.e. published after effective date but filed prior effective date)?** **"Conflicting applications" / "secret prior art"**	Post AIA 35 U.S.C. §102 (a) (2): all prior art is considered; [except when originating from inventor within grace period (no "self-collision") or when same subject matter, originating from inventor, was previously publicly disclosed within grace period] "Full" prior art (novelty and inventive step)	Patent Act, 28.2 (c) and (d): CA or PCT-CA applications, only applies to disclosures made by a third party Prior art only in regard to novelty	Art. 54(3) EPC: EP patent application or PCT-EP (filing fees must have been paid, translation, if applicable "self-collision" with own parallel prior rights of <u>the same priority</u> no longer possible (G 1/15) prior art only in regard to novelty ("photographic novelty")	JP patent application or utility model, PCT appl. designating JP and (translated into / in) Japanese Art. 29, Par.1 JPL [**except** if same inventor/applicant (no "self-collision") Art.29-bis JPL] Prior art only in regard to novelty (but: "substantially the same" also included as novelty-relevant)	CN patent application or utility model / PCT application entering CN phase; "secret" prior art not considered Prior art only in regard to novelty (but: "substantially the same" also included as novelty-relevant)	KR patent application or utility model or PCT-KR application in KR or translated into KR [**except** if same inventor/applicant (no "self-collision")] Prior art only in regard to novelty (but: "substantially the same" also included as novelty-relevant)
<u>Novelty:</u> **Double patenting objection?**	double patenting objection is relevant – claims of co-owned patents must be patentably distinct (i.e., non-obvious)	double patenting objection is relevant – claims of co-owned patents must be patentably distinct (i.e., non-obvious) = self-collision	No statutory double patenting rejection; however, identical claims within one family claiming the same priority are not admissible (according to case law)			

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<u>Novelty:</u> **Non-prejudicial disclosure / grace period**	12 months from first filing for inventor's own disclosure	12 months from CA or PCT-CA application for disclosure by inventor/applicant or disclosure by someone who obtained knowledge directly from the inventor/applicant Note CA Patent Act is being amended within the next year or so to change the grace period from CA/PCT-CA filing date to priority date	6 months from filing for disclosure based on - display at "recognized" exhibitions - evident abuse in relation to application (Art. 55 EPC)	6 months from filing for disclosure based on - international exhibition - test/presentation in writing by person with right to invention - evident abuse (Art. 30 JPL)	6 months from filing for disclosure based on - international exhibition - academic meeting - evident abuse	**New**: 12 months grace period for evident abuse and disclosure by person with right to obtain patent
<u>Novelty:</u> **Disclaimer**	Disclaimers are generally permitted	Disclaimers are generally permitted	"Disclosed" and "non-disclosed" disclaimers are allowable, in principle, but under narrow conditions, for: - conflicting applications under Art. 54(3) EPC (see above) - "chance anticipation" - excluding patent-exempt subject matter /"non-human")	Disclaimers are generally allowable, for example in - "accidental" prior art - excluding patent-exempt subject matter /"non-human") (requirements less strict than in proceedings before EPO)	Usually not permitted (except in case of overlapping ranges and to exclude patent-exempt subject-matter)	Disclaimers are generally permitted

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<u>Novelty:</u> **Hitherto Unknown Use of a Known Product Patentable?**	Patent protection is available for new uses of previously known compounds. typically expressed as “method” claims.	Yes. “Use of X for Y” in the case of medical uses, or “method of using X for Y” in the case of non-medical uses. “Product X for doing Y” would also be patentable.	Yes [“second non-medical use”: G2/88 (known compound known to be used in a certain composition can be claimed to be used for hitherto not known use/effect in the same composition)]; however: scope of protection does not encompass the already known compound but only its manifest preparation for said use	Yes (medical use, but also cosmetic and food uses, for example) Use of a known compound can be pursued by, for example, a composition claim	Yes.	A use invention, which claims a new use of a known material in accordance with its inherent but newly found property, may be patentable.

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<u>Inventive step:</u> **Established test or practical guidance for the assessment of inventive step?**	basic test for obviousness: "*Graham v. John Deere*": (1) Determine scope and content of the prior art; (2) Ascertain differences between claimed invention and prior art; (3) Resolve the level of ordinary skill in the pertinent art; (4) Consider objective indicia of non-obviousness (i.e., are there secondary considerations that rebut obviousness) *KSR v. Teleflex* modified the *teaching, suggestion or motivation test* to include judging whether a combination of elements would produce predictable results	Apotex Inc. v. Sanofi-Synthelabo Canada Inc., 2008 SCC 61, restated the Windsurfing test: (1) Identify the skilled person and his common general knowledge; (2) Construe the claim; (3) Identify the differences between the art and the construed claim; (4) Viewed without any knowledge of the invention as claimed, do those differences constitute steps that would have been obvious to the skilled person? "Obvious to try" can be raised in the final step and requires a finding that it was more or less self-evident to try to obtain the invention as claimed.	**"problem-solution"-approach**: determine closest prior art; Determine "surplus" feature(s) and technical effect associated therewith; Develop "objective problem" and whether it would have been obvious to arrive at the proposed solution Problem also may be "providing an alternative", even in this case, it needs to be assessed whether skilled person "would" have picked the claimed solution **"could/would"-**approach: skilled person does not venture "randomly" but has objective (may need pointer)	(Examination Guidelines) Inventive step is determined by considering whether or not it could be **reasoned** that a skilled person "easily" arrives at the claimed invention based on the prior art. Select the prior art most suitable for the reasoning (**primary prior art**) and taking account of the differences between the claimed invention and the primary prior art, determine whether or not the **reasoning** is possible, based on various factors, by adopting **secondary prior art** or considering the **common general knowledge**. If the **reasoning** is determined to be possible, inventive step is denied.	(1) Determining the closest prior art; (2) Determining the distinguishing features of the invention and the technical problem actually solved by the invention; (3) Determining whether or not the claimed invention is obvious to a person skilled in the art.	(1) choose prior art, which is the closest to the claimed invention. (2) determine whether invention described in the claims could have been easily made by a skilled person (despite the difference between the claimed invention and the cited art). Consider whether, for the skilled person, the claimed invention has any **advantageous effects** over the cited prior art, mainly focusing on ① whether the cited prior art <u>provides any motivation</u> to a person skilled in the art to arrive at the subject matter of the claimed invention or ② whether the difference between the prior art and the claimed invention can be considered as a mere exercise of ordinary creativity.

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<u>Inventive step:</u> **Secondary indicia, if any, that are taken into account**	Evidence of commercial success, long-felt but unsolved needs, failure of others, copying by the industry and unexpected results.	Taken into account under the "obvious to try test": extent, nature and amount of effort required to achieve the invention, are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine, are there a finite number of identified predictable solutions known to persons skilled in the art, the actual course of conduct which culminated in the making of the invention	Secondary indicia are considered, in principle; however: do not take precedence over problem-solution approach (indicia are otherwise similar to US practice)	Advantageous effect Teach-away Commercial success (provided that it's not derived from sale promotion or the like)	Secondary indicia are considered, in principle; however, do not take precedence over the above approach [steps (1) through (3)].	Commercial success or favorable comments from the industry or the fact that the claimed invention had not been implemented by anybody for a long time prior to filing may be regarded as indicative of the inventive step (secondary evidence). However, those facts *alone* are not to be regarded as indicative of inventive step. Rather, inventive step should be determined based on the specification (i.e., the objective, structure, and effect of the invention), commercial success is not to be regarded as a reference for the determination of inventive step, if success does not derive from the technical features of the invention but from other factors (e.g., improvement in sales techniques or advertising).

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<u>Inventive step:</u> **Comparative experiments (allowable / necessary?)**	No requirement for providing experimental evidence. May be useful to show unpredictable results. May also be useful to enable an invention and to avoid arguments about “undue experimentation”. May be submitted post filing in a 132 affidavit.	No requirement, but can be introduced post-filing to substantiate statements about the differences between the claimed invention and the art. However, post-filing data to support enablement not allowed.	Examiners often require comparative experiments, in particular in the chemistry/pharma area, if claimed subject-matter differs from prior art by only one feature; Comparative experiments tests (and, in fact any data) supporting inventive step **can be introduced post-filing**, at any stage (if tied to an effect / advantage as originally disclosed) However, post-filing data to support enablement not allowed	Comparative experiments are helpful in supporting inventive step. Similar to EP, comparative experiments tests or published scientific articles supporting inventive step **can be introduced post-filing**, at any stage (if tied to an effect / advantage as originally disclosed)	Post-filed data are now available in CN, but only if technical effect underlying data is "obtainable" to skilled person from the original disclosure	It is not necessary to submit comparative experimental data when filing a selective invention to prove the inventiveness. The applicant can argue with the examiner using comparative experiment data to prove the inventiveness of his invention during the examination procedure.

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<u>Enablement</u>, written description requirements	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 full scope of the claimed invention without "undue experimentation."	Subsection 27(3) Patent Act: spec. must correctly and fully describe the invention and its operation or use; skilled person must be able to operate the invention using only his common general knowledge and the spec. "Promise doctrine" is being abandoned	Art. 83 EPC: At least one way to work invention must be disclosed; If (broad) ranges are claimed: invention must be enabled over essentially the whole range claimed; enablement is judged by assessing entire disclosure, at the time of filing	Art. 36, Par.4; Art. 36, Par.6, Item 1 JPL In principle, evidence such as experimental data supporting enablement and written description requirements **cannot be introduced post-filing** Lack of these requirements can constitute grounds for nullity actions including in opposition and invalidation trials.	At least one way to work invention must be disclosed; If (broad) ranges are claimed: invention must be enabled over essentially the whole range claimed; enablement is judged by assessing entire disclosure, at the time of filing	[Enablement Requirement] The description of an invention shall be written clearly and complete so that a person with ordinary knowledge in the art to which the invention pertains easily understands the concerned invention. Specifically for chemical substance invention, description shall include the detailed response conditions necessary for manufacturing the substance invention such as the starting material, temperature, pressure, inflow and outflow and the result of the direct experiment under such conditions.

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Clarity / definiteness requirements	35 USC 112 – a patent application shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his or her invention.	Subsection 27(4) Patent Act – claims must define distinctly and in explicit terms the subject-matter of the invention Section 84 Patent Rules – claims must be clear and concise and fully supported by the description “Lack of clarity” is common objection in Examination, but is rarely a successful attack in invalidity proceedings. The courts aim to construe the claims in a meaningful way	Art. 84 EPC: The claims must be "clear and concise" as read by themselves (i.e. without reference to the description); “Lack of clarity” is common objection in Examination, but only limited role post-grant (not a ground of opposition / nullity) “problematic” under Art. 84 EPC: reach through claims, functional features reflecting (only) a desirable result	Art. 36, Par.6, Items 2 and 3 JPL The claims must be "clear and concise". Technical meaning of the feature specifying the invention should be interpreted not only based on the statements of the claims, but also with reference to the description and the common technical knowledge at the fling date. In principle, product-by-process claims lack clarity (acceptable if any reason that it is impossible and infeasible to specify the product by its structure exists) Estoppel may apply to any objection made in the examination stage.	Both individual claim and the claims as a whole must be clear	[Art. 42] The claims shall define the invention clearly and concisely.

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Patentability of functional features	"means-plus-function" limitation (i.e. functional function may be limited to structural embodiments disclosed in description)	functional features are patentable, in principle (although initially often objected to as “lacking clarity”) reach-through functional features and *"result-to be-achieved"*-type features are generally rejected by Examiners but are in practice permissible and patentable if the “result to be achieved” is not at the point of invention	functional features are patentable, in principle (although initially often objected to as “lacking clarity”) (case law and practice indicate that reach-through functional features and *"result-to be-achieved"*-type features are generally not allowable)	functional features are allowable, provided that their “scope” is clear. (construed by reference to the description and the common technical knowledge at the fling date.)	"product-plus-function" limitation allowable (however, pure functional limitation is generally not allowable).	Basically, functional claims are not allowable. However in the following cases the invention is deemed to be clear even with functional expressions and the claims may be allowed. (1) expressing claims functionally is necessary since the technical idea of the invention cannot be clearly described “structurally” (2) where the meaning of the functional expressions is clearly specified by the detailed description of the invention and in drawings.