Sufficiency of Patent Disclosure in BRICS

Ji Liu
CCPIT Patent and Trademark Law Office, China
contributed by
Pankaj Soni
Remfry & Sagar, India
Yury Kuznetsov
Gorodissky & Partners, Russia
Pieter Visagie
Adams & Adams, South Africa
Rana Gosain
DANIEL ADVOGADOS, Brazil

BRICS IP Forum 2014
October 30 to 31, 2014

Questions to discuss

- ***Statutory Basis***
- ***Practice Standards***
- ***Statistics***
- ***Recent/Expected Changes in Law/Practice***
- ***Case Review***

Statutory Basis

CHINA

Article 26.3 of Chinese Patent Law

> The description shall set forth the invention or utility model in a manner sufficiently clear and complete so as to enable a person skilled in the relevant field of technology to carry it out; where necessary, drawings are required. The abstract shall state briefly the main technical points of the invention or utility model.

- Art. 26.3 doesn't explicitly mention possession by the filing date. But the disclosure of the description, according to Chinese patent practice, should reasonably convey to those skilled in the art that the applicant has completed the invention before the filing date.

Practice Standards CHINA

SIPO Guidelines for Examination (Part II Chapter 2 Section 2.1.3)

> The description shall enable a person skilled in the art to carry out the invention or utility model. It means that the person skilled in the art can, in accordance with the contents of the description, carry out the **technical solution** of the invention or utility model, solve the **technical problem**, and achieve the expected **technical effects**. (factors: problem + solution + effect)

Practice Standards

CHINA

Examples of insufficient disclosure, as enumerated in the Guidelines for Examination of SIPO, include the following:

…

> (5) the description sets forth a concrete technical solution but without experimental evidence, while the solution can only be established upon confirmation by experimental result. For example, in general, the invention of a new use for a known compound requires experimental evidence in the description to validate the new use and effects thereof; otherwise, the requirement of sufficient disclosure cannot be met.

Practice Standards

CHINA

- For inventions relating to new compounds (including compound *per se*, intermediate, composition, use or preparation method), **regardless of what is being claimed**, the following experimental information should be disclosed within the Examples section:
  - preparation method
  - identification
  - use/effect (e.g. activity)

  of the new compound(s).

  - Regarding preparation method, it should relate to the preparation of specific compound(s).

Practice Standards

CHINA

- Regarding experimental data in connection with identification, the information shall be directed to specific compound(s) too.

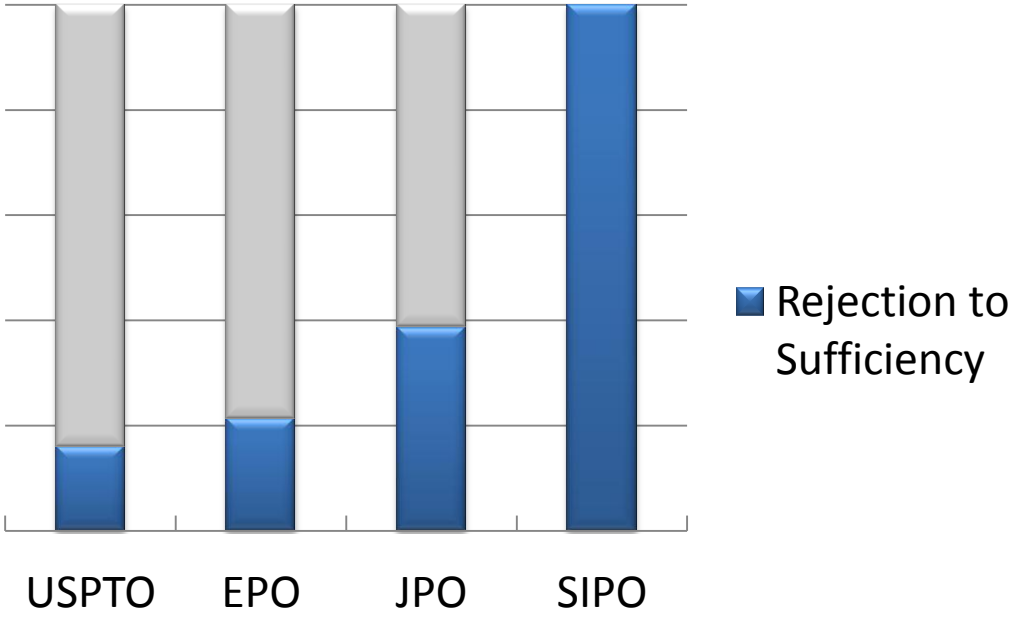
- Regarding experimental data in connection with use/effect (activity), what needs to be clearly disclosed includes:
  - the detailed information about the experiment and data thereof
  - from what compounds were those data obtained

- Post-filing date experimental evidence is not acceptable (partially changed since late 2013).

Statistics

CHINA

- *The requirement on experimental evidence in SIPO is much stricter than those in USPTO, EPO and JPO.*

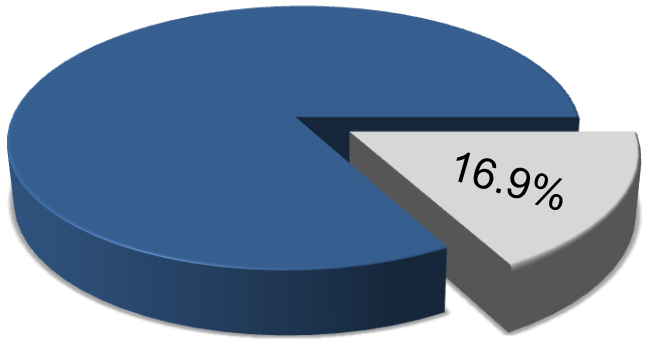


For applications that are rejected in China due to the deficiency in experimental evidence, only 16.1%, 21.4% and 38.7% of their counterpart applications in US, Europe and Japan, respectively, were queried to be not sufficiently disclosed.

Statistics

CHINA

- *The strict standard of SIPO on sufficient disclosure resides not only on the necessity of disclosing experimental data, but much more on rigorousness of evidence recited in the description*



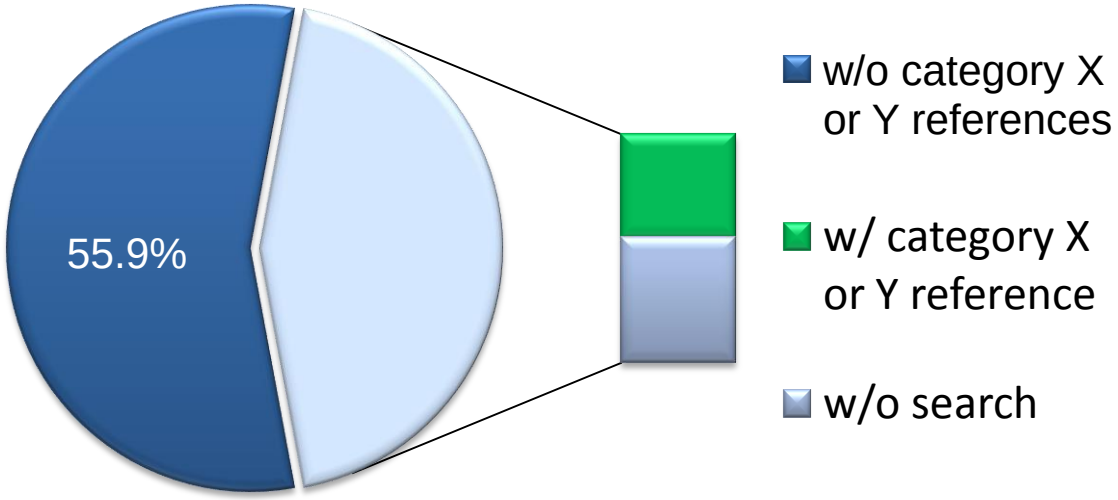
Among the applications rejected due to the deficiency in experimental data, only 16.9% of the applications do not have any experimental data. Most of the applications are rejected because the examiners think the data are not eligible or ample to meet the requirement.

Statistics

CHINA

- *In practice, the examiners of SIPO are more accustomed to examine sufficiency (Article 26.3), instead of inventive step (Article 22.3).*

Note: expected to change in the next few years.



Among the applications rejected for insufficient disclosure w/o necessary experimental data, only 55.9% of them relate to new compounds or use that do not have relevant prior art references. Some improvement inventions relating to similar compounds, new crystal or dosage form are rejected due to insufficient disclosure, instead of obviousness, even w/ category X or Y references found or even w/o search.

Recent Changes

CHINA

- *The Patent Affairs Administration Department of SIPO held a "News Briefing on Patent Examination in SIPO" on December 4, 2013*
  - Standard of sufficient disclosure
  - Relationship between sufficient disclosure and data

Recent Changes CHINA

- *1. Examination should focus on "novelty, inventiveness and practical applicability".*

  For inventions complying with those three requirements, examination strategy shall be formulated and implemented with the aim of granting patent right, so as to achieve the legislative purpose of the Patent Law, i.e., encouraging innovation.

- *2. It is made clear that the facts and evidence must be distinguished when examining whether a patent application meets the requirements of sufficient disclosure.*

Recent Changes

CHINA

- *(1) Facts: the technical solution of the claims*

  The examination on sufficient disclosure should be directed to the technical solution of the *claims* and what should be judged is whether the technical solution can be carried out at the *date of filing* on the basis of the *original* description and claims.

Recent Changes CHINA

(2) *Experimental data: necessary? Facts or evidence?*

- Experimental data are often used to prove that the technical solution indeed has the use or effect alleged by the applicant, and it is very clear that *such experimental data are not the technical solution per se or a part thereof*.
- However, *if the technical solution can only be established upon confirmation by experimental results*, then experimental data *must* be provided in the *original* description. For example, with regard to a new use for a known compound, inclusion of experimental data in the original description is usually essential.
- The Examination Guidelines does not correlate the *format* of the experimental data with the sufficient disclosure. The requirements in the previous internal examination instructions of SIPO regarding the format of experimental data are no longer effective.

Recent Changes

CHINA

- *(3) Post-filing experimental data:*

  As to the post-filing experimental data submitted by the applicant, for those belonging to *evidence*, it *shall be considered* during the patent examination. The post-filing data submitted should meet the requirements of evidence about authenticity, relevancy and legitimacy.

Recent Changes

CHINA

- *3. The different versions of Patent Examination Guidelines issued by SIPO are bound by Article 84 of the Legislation Law. That is to say, a new version of Patent Examination Guidelines is not retroactive to old cases.*

Example of changes in Guidelines:

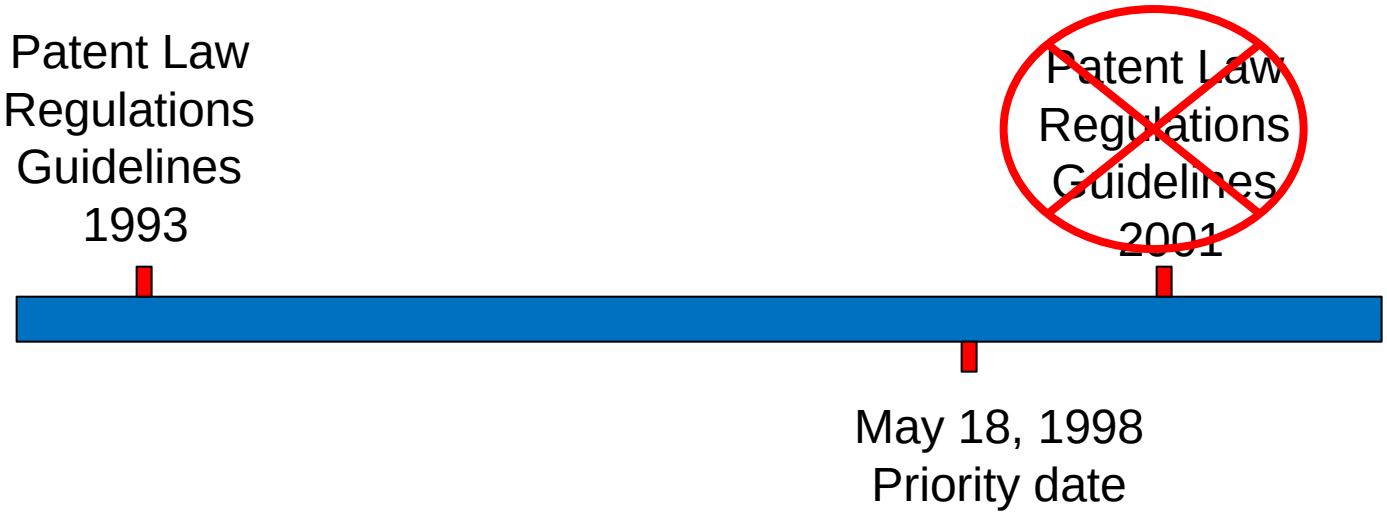
	Lack of experimental data
Guidelines 1993:	*Lack of practical applicability*
Guidelines 2001:	*Insufficient disclosure*
Guidelines 2006:	*Insufficient disclosure*
Guidelines 2010:	*Insufficient disclosure*

Beijing High Court Case (2014.5.15)

- *Novartis (represented by CCPIT) v. PRB*
- *Facts:*
  - *Invention: Compound A + Compound B >> A or B (synergistic effect)*
  - *Effect: General description, no experimental data.*
    - ✓ *"Combination therapy results in a more effective antihypertensive therapy"*
    - ✓ *"The available results indicate an unexpected beneficial effect of a combination according to the invention"*
  - *Patent Reexamination Board Decision: insufficient disclosure under the Patent Law 2001 and the corresponding Guidelines.*

Beijing High Court Case (2014.5.15)

- *Novartis (represented by CCPIT) v. PRB (cont'd)*
  - *Opinions of Beijing High Court*
    - Patent Law, Regulations and Guidelines are not retroactive



Beijing High Court Case (2014.5.15)

- *Novartis (represented by CCPIT) v. PRB*
  - *Opinions of Beijing High Court*
    - *Guidelines 1993 allow post-filing data to prove effects*
    - *Lack of experimental evidence: lack of industrial applicability*
    - *Post-filing data can be submitted for the Examiner's reference when assessing patentability (including industrial applicability)*
  - *Decision: post-filing data can be used to prove the effects of the invention in this case.*

Case Review: CHINA

- *PRB Case number: 1F124572*
  - *Invention Title:*

Heterocyclic-substituted alkanamides useful as renin inhibitors

  - *Claims: 128 compounds (omitted)*

Case Review: CHINA

- Description:
  - Alkanamides useful as medicaments were disclosed in eg. EP 0678503. However, especially for renin inhibitors, highly-effective active ingredients are needed. The purpose of the invention is to improve pharmacokinetics like absorption, metabolic stability, solubility or fat-solubility.
  - The description provides in the Examples the methods for preparing 128 compounds.

Case Review: CHINA

- Description (cont'd):
  - The description contains the following depictions on the effect of the compounds, i.e. "The compounds of the present invention have blood pressure-lowering effect in the described *in vivo* test with i.v. doses of about 0.003 to about 0.3 mg/kg and with oral doses of about 0.3 to about 30 mg/kg" and "The compounds of the present invention show inhibitory effects in the *in vitro* systems at minimal concentrations of about 10^{-6} to about 10^{-10}mol/l".

Case Review: CHINA

- Rejection Decision made by the Examining Division:
  - The present application relates to a class of compounds useful as renin inhibitors. Since it is generally difficult to predict the use of a compound as medicament and/or technical effect thereof, it has to be verified by experimental results.

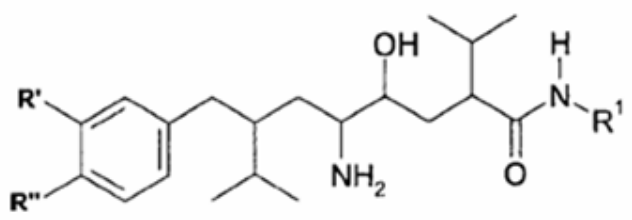
Case Review: CHINA

- Rejection Decision (cont'd):
  - Although the present application discloses the preparation and characterization of the compounds, for their use as renin inhibitor, the description only generally describes their effects *(as indicated in the last page)*. Said two assertive conclusions do not clearly indicate which compound(s) were used to obtain varying results. Thus, a person skilled in the art cannot determine that the compounds as claimed have the effect as alleged by the applicant, merely upon the depictions above. Also, no prior art helps to deduce the conclusion. Hence, the description of the present application is insufficiently disclosed.

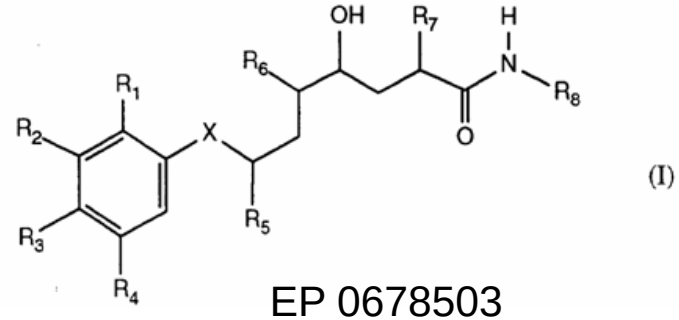
Case Review: CHINA

Question: ***Whether it belongs to a technical solution that can only be established upon corroboration by experimental result?***

- Compared with EP 0678503 (category A reference)



The Invention



EP 0678503

- EP 0678503: In the in vitro systems, the compounds exhibit inhibitory activities at minimum concentrations of from approximately 10^{-6} to approximately 10^{-10} mol/l, and in the in vivo test described, the compounds of the present invention have blood pressure-lowering effect at doses of from approximately 0.003 to approximately 0.3 mg/kg i.v. and at doses of from approximately 0.3 to approximately 30 mg/kg p.o.

Case Review: CHINA

Question: ***Whether it belongs to a technical solution that can only be established upon corroboration by experimental result?***

- A person skilled in the art, based on the disclosures contained in the description of the present application in combination with the situation analysis of the prior art (i.e. the structure similarity of the present compounds to D1 compounds), can conclude that the compounds of the present application and the compounds known in the prior art have the same or similar effect, and the present invention does not belong to the circumstance where a technical solution can only be established upon corroboration by experimental result .

- **PRB Decision:** Decision of Rejection was revoked.

Statutory Basis

INDIA

Section 10(4) of The Patents Act, 1970

"Every complete specification shall—

(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;

(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and

(c) end with a claim or claims defining the scope of the invention for which protection is claimed;

(d) be accompanied by an abstract to provide technical information on the invention:….."

Practice Standards

INDIA

- Claims should be fully supported by the accompanying description and drawings;
- Enable a person possessing average skill in, and average knowledge of, the art to which the invention relates, without requiring any further innovative faculties to work the invention;
- Insufficiency is a valid ground for **pre-grant opposition** under Section 25(1)(g),for **post-grant opposition** under Section 25(2)(g); and
- Insufficiency is a valid ground for **revocation** of patent under Sections 64 (1)(h), 64(1)(i) and 64(1)(p)

Practice Standards

INDIA

- Sections 57-59 of our Act – Amendments are Permitted to Remedy the Deficiency

> Section 59(1) - No amendment of an application for a patent…shall be made except by way of **disclaimer, correction or explanation**, and no amendment thereof shall be allowed, except for the purpose of **incorporation of actual fact**, and no amendment of a complete specification shall be allowed…[which]…would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or … would not fall **wholly within the scope** of a claim of the specification before the amendment.

Practice Standards

INDIA

Inclusion of prophetic example

- The Act is silent on whether an example mandatorily needs to be a working example based on results achieved in a laboratory or a prophetic or paper example based on predictive results.
- The Draft Manual on Patent Practice states that examples must be included especially in the case of chemical related inventions.
- Therefore, as a matter of practice, examples are allowable irrespective of whether it is working or prophetic/paper, the operating consideration being that the **example must enable a person having ordinary skill in the art to carry it into effect without using any further innovations or thoughts**.

Expected Changes in Law/Practice

INDIA

- Section 3(d) of our Act renders unpatentable a new form of a known substance which does not result in the enhancement of the known **efficacy**, unless such new form differs significantly in properties with regard to efficacy.

- *Novartis v. Union of India* (Supreme Court) – experimental data to establish therapeutic efficacy has to be included in the specification in order to meet **efficacy** requirements.

Statutory Basis

RUSSIA

Article 1350 of the Civil Code

"1. …. Legal protection is granted for an invention which is new, has inventive level and is industrially applicable.

4. Invention is industrially applicable if it can be used in industry, agriculture, health care and other fields of economy or social environment"

Article 1375 of the Civil Code

"2. Application for invention shall comprise:

…

2) specification of invention disclosing it with ***completeness sufficient*** for implementation; …"

Practice Standards

RUSSIA

- Sufficiency of disclosure traditionally is a part of industrial applicability consideration
- Industrial applicability is examined first, before conducting search and novelty and inventiveness examination
- General scheme of ***industrial applicability test*** during examination:
  - Checking whether the specification contains definition of a purpose of invention
  - Checking whether specification of invention or publicly available prior art contain description of means and methods for invention implementation
  - Checking whether being implemented the invention is capable to serve for the defined purpose

Practice Standards RUSSIA

- Failure to pass the tests results in rejection of the application
- Same test is used during patent invalidation considerations

Brief overview of the test

- ***When checking a definition of purpose***
  - Purpose is to preferably be defined in specification and mandatorily in independent claim(s)
  - Real necessity or demand in market is irrelevant
- ***When checking specification for disclosure of means and methods for implementation***
  - The specification shall disclose all means and methods required to implement invention
  - Means and methods may not be specifically disclosed if they are publicly known in art before the priority date of invention
  - Means and methods may not be publicly known in art but may relate to a type for which are known rules and methods of their making/selecting

Practice Standards

RUSSIA

- ***When checking whether being implemented the invention is capable to serve for the defined purpose***
  - Independent claim shall characterize invention capable to implement purpose
    - Absence of parts or steps accomplishing apparatus or method causes their rejection
  - Experimental data may be presented for confirmation of capability to implement the purpose
  - Experimental data ***are required*** for applications for medicals (data obtained on relevant models)
  - If only experimental data can prove capability to implement the purpose, their sufficiency for all embodiments

Statistics

RUSSIA

- Rejection/Invalidation basing of non-correspondence to industrial applicability is a rare one

- According to the recent Russian PTO statement the sufficiency of disclosure standard shall be raised

Recent Changes (October, 2014)

RUSSIA

Inventions

- Novelty
- Inventive Level
- Industrial Applicability
- **Sufficiency of disclosure**

Utility models

- Novelty for the Combination of Essential Features
- Industrial Applicability
- **Sufficiency of disclosure**

Expected Changes in Law/Practice

RUSSIA

- *New Patent Regulations are under preparation*
  - *New expanded provisions of Sufficiency of disclosure are expected*
  - *However announced at the Annual Meeting (October 2014) that the approaches will be "largely based on elaborated experience as well as on modern practice of the leading patent offices with regard to sufficiency of disclosure requirement"*

Statutory Basis

SOUTH AFRICA

Sufficiency

Section 32(3)(b) A complete specification shall sufficiently describe, ascertain and, where necessary, illustrate or exemplifiy the invention and the manner in which it is to be performed in order to enable the invention to be performed by a skilled person in the art of such invention

Section 61(1)(e) Any person may apply for the revocation of a patent on the ground that the complete specification does not sufficiently describe, ascertain and, where necessary, illustrate or exemplifiy the invention and the manner in which it is to be performed in order to enable the invention to be performed by a skilled person in the art of such invention

Statutory Basis

SOUTH AFRICA

Utility

Section 61(1)(d) Any person may apply for the revocation of a patent on the ground that the invention as it is illustrated or exemplified in the complete specification concerned cannot be performed or does not lead to the results and advantages set out in the complete specification.

Fair basis

Section 32(4) The claims of a complete specification shall ... be fairly based on the matter disclosed in the specificaton

Section 61(1)(f) Any person my apply for the revocation of a patent on the ground that the claims of the complete specification concerned are not fairly based on the matter dislcosed in the specification.

Practice Standards

SOUTH AFRICA

Disambiguation

- For South Africa, distinctions must be drawn between:
  - Insufficiency
  - Inutility
  - Lack of fair basis in the claims
- Distinct meanings in terms of the Patents Act
- Statutory grounds of patent revocation
- No examination
- Enquiry into each matter begins with a construction of the claims

Practice Standards

SOUTH AFRICA

Insufficiency

- Specification must describe the invention sufficiently for the skilled person to be enabled to perform that invention - Non-compliance is a ground for revocation
- Question of fact: Does the specification contain proper instructions for it to be put into use by the skilled person?
- Omitted essential instructions could point to lack of sufficiency
- Achieving the results set forth, or not, is irrelevant
- Skilled person is assumed to know the state of the art and of being capable of carrying out routine experimentation
- Expert evidence is admissible to assist the court

Practice Standards

SOUTH AFRICA

Inutility

- Section 60(1)(d) – a patent is revocable if the invention as it is illustrated or exemplified in the specification cannot be performed or does not lead to the results and advantages set out in the specification
- Question of fact: Can the invention be performed in the manner illustrated or exemplified and, if it can be so performed, does it lead to the advantages that are set out?
- The enquiry is not limited to the actual drawings and/or examples presented in the specificaton.
- Inutility of any particular embodiment of a patented invention could cause the entire patent to be invalid

Practice Standards

SOUTH AFRICA

Lack of fair basis

- Claim/s of a complete specification is/are required to be fairly based on the matter disclosed in the specification
- The existence of strict and direct basis is not required
- No claim may be for something that is not covered by the general or generalised disclosure of the invention
- Questions used by the court in guiding its assessment of fair basis include:
  - Is the alleged invention as claimed in a concerned claim broadly described in the specification?
  - Is there anything in the specification that is inconsistent with the alleged invention as claimed in that claim?
  - Does the claim include as a characteristic of the invention any feature as to which the specification is wholly silent?

Practice Standards

SOUTH AFRICA

Comments

- Inutility / insufficiency is decided relying heavily on the evidence adduced in guiding the court
- No clear rules for the drafting of specifications can be derived from the *dicta* dealing with these grounds
- Deficiencies in a specification resulting in insufficiency can be addressed by way of a “supplementary disclosure” entered after grant in terms of Section 51(8)
- Material misrepresentation may be an issue if the applicant was or should reasonably have been aware of deficiencies in the specification at the time of making the prescribed declaration (Form P3)
- Such a material misrepresentation cannot, generally speaking, be cured after grant

Statutory Basis

BRAZIL

Article 24 of Brazilian Patent Law

"The specification must describe the subject matter of the invention clearly and sufficiently so as to enable a person skilled in the art to carry it out and to indicate, when applicable, the best mode of execution of the invention.

Sole Paragraph - In the case of biological material essential for the practical execution of the subject matter of the application, which cannot be described in the form of this article and which has not been accessible to the public, the specification will be supplemented by a filing of the material in an institution authorized by BRPTO or indicated in an international agreement.

Statutory Basis

BRAZIL

The descriptive sufficiency is also defined in Brazilian Examination Guidelines

> The descriptive sufficiency should be evaluated based on the specification, it must disclose the invention in a manner sufficiently clear and precise, so that it is reproduced by a man skilled in the art. The specification must contain sufficient conditions that ensure the achievement of the invention.

Nullity of Brazilian Patent

Nullity of a patent will also be declared administratively when the specification do not describe the subject matter of the invention clearly and sufficiently.

Comparison

CN	IN	RU	ZA	BR
Is insufficient disclosure a ground for oppose or invalidate a patent?				
Yes	Yes	Yes	Yes	Yes
Can insufficient disclosure be remedied by submitting additional information, for example further experimental evidence, which experiments are conducted after the filing date?				
Basically No*	NO*	Yes	Yes, but not after grant	Yes
For chemical invention, e.g. new compounds, is the applicant required to disclose the experimental data relating to characterization? Then is the applicant required to disclose experimental data relating to the effect? E.g. efficacy?				
Yes, Yes	Yes, Yes	Yes	Advised, but not strictly required	Yes

Comparison

CN	IN	RU	ZA	BR
Is paper or prophetic example acceptable in your country?				
Risky	No/Unclear	Basically yes	Yes, but guard against inutility	Yes
Is sufficiency requirement a strict requirement in your country for chemical inventions?				
Yes	Yes (it Depends)	Yes	Moderate	Yes

Ji LIU
Patent Attorney

CCPIT Patent and Trademark Law Office
10/F, Ocean Plaza
158 Fuxingmennei Street
Beijing 100031 China
Tel: +86-10-66412345
Fax:+86-10-66415678
Email: liuji@ccpit-patent.com.cn

Yury Kuznetsov
Partner/Patent Attorney

Gorodissky & Partners
B.Spasskaya Str., 25, bldg. 3 Moscow 129090, Russia
phone: +7 (495) 937-6116
fax: +7 (495) 937-6104
KuznetsovY@gorodissky.ru
www.gorodissky.com

Thank you!

Pankaj Soni
Partner/Attorneys-at-law

Remfry & Sagar
Remfry House at the Millennium Plaza,
Sector 27, Gurgaon - 122 009
New Delhi National Capital Region, India
Tel: 91-124-280-6100, 91-124-465-6100
Fax: 91-124-280-6101, 91-124-257-2123
Video Call: 91-124-465-6115
E-mail: remfry-sagar@remfry.com

Pieter Visagie
Partner/Patent Attorney

Adams & Adams
Lynnwood Bridge 4 Daventry Street Lynnwood Manor
Pretoria, 0081
PO Box 1014 Pretoria 0001
South Africa
Tel:+27 12 432 6000
Fax:+27 12 432 599
mail@adamsadams.com

Rana Gosain
Partner/Patent Attorney

DANIEL ADVOGADOS
rana.gosain@daniel.adv.br
Direct Tel: 55 21 2102-4205
patents@daniel.adv.br
Tel: 55 21 2102-4212 –
Fax: 55 21 2524-3344
Av. Republica do Chile 230 –
3º andar – Centro, Rio de Janeiro – RJ – Brasil – CEP: 20.031-170
http://www.daniel.adv.br