Questions

I. Current law and practice

Groups are invited to answer the following questions under their national laws. If those national and regional laws apply to a set of questions, please answer the questions separately for each set of laws. Please number your answers with the same numbers used for the corresponding questions.

1) Does your country permit patents covering any aspect of new uses of known pharmaceutical compounds (hereafter referred to as second medical use claims)?

Yes, patents covering certain aspects of new uses of known pharmaceutical compounds are permitted in China.

If yes, please answer Questions 2) to 7) inclusive before proceeding to the questions in Parts I and II. If no, please proceed directly to the questions in Parts II and III.

2) If the answer to Question 1) is yes, please answer the following sub questions.
   a) What is the basis for patent protection?

   According to the provisions on the types of use claim in the Section 4.5.1 Chapter 10 Part II of the Guidelines for Patent Examination (2010 Edition): The invention relating to the use of a chemical product is made on the basis of discovery of a new property of the product and the use of such property. Hence,
a use invention is an invention of process, and its claim is a process claim.

According to the provisions on claims of medical use of substance in the Section 4.5.2 Chapter 10 Part II of the Guidelines for Patent Examination: An application relating to the medical use of a substance shall not be granted if its claim is drafted in the wording “use of substance X for the treatment of diseases”, “use of substance X for diagnosis of disease” or “use of substance X as a medicament”, because such claim is one for “method for diagnosis or for the treatment of diseases” as referred to in Article 25.1(3). However, since a medicament and a method for the manufacture thereof are patentable according to the Patent Law, it shall not be contrary to Article 25.1(3) if an application for the medical use of a substance adopts pharmaceutical claim or use claim in the form of method for preparing a pharmaceutical, such as “use of substance X for the manufacturing of a medicament”, “use of substance X for the manufacturing of medicament for the treatment of a disease Y” and so on.

The above provisions in the Patent Law and in the Guidelines for Patent Examination are recognized in legal practice in the Chinese courts.

b) What types of second medical use are patentable? See, for example, paragraphs 14) - 17) above/WGLs.

According to the provisions of the Guidelines for Patent Examination (2010 Edition), the circumstances listed in the paragraphs (14)-(16) of the Working Guidelines all are patentable. That is to say, the following secondary medical uses are patentable:
-- as for known substances with successfully developed first medical use, their second medical uses are patentable;
-- as for known substances for which the first known medical use did not succeed, their second medical uses are patentable;
-- as for known substances with previously discovered non-medical use, their medical uses are patentable; and
-- as for substances without any discovered use, their medical uses are patentable.

c) Are any types of second medical use impermissible subject matter? See, for example, paragraphs 14) - 17) above/WGLs.

According to the provisions in the Section 5.4 Chapter 10 Part II of the Guidelines for Patent Examination, inventions relating to medical use may not be patentable due to lack of novelty depending on the following aspects:
(1) Whether or not the new use is different in substance from the known use. The use invention does not possess novelty when the difference between the new use and the known use lies merely in the form of expression, but the
substance of them is the same.

(2) Whether or not the new use is revealed directly by the mechanism of action or pharmacological action of the known use. The use does not possess novelty if it is directly equivalent to the mechanism of action or pharmacological action of the known use.

(3) Whether or not the new use belongs to generic (upper level) term of the known use. The known use defined by specific (lower level) term may destroy the novelty of the use defined by generic (upper level) term.

(4) Whether or not the features relating to use, such as the object, mode, route, usage amount, interval of administration can define the procedure of manufacture of a pharmaceutical. The distinguishing features merely present in the course of administration do not enable the use to possess novelty.

With regard to above item (4) of the Guidelines, although it was deemed in the final decision (Administrative Judgment (2008) GaoXingZhongZi No.378, Beijing High Court) which is directed to the patent invalidation case of Merck Co. that administration technical features such as “dosage form and administration dose” in a medical-use claim should be considered, the Supreme Court in a Retrial Ruling (see Administrative Ruling (2012) ZhiXingZhongZi No.75) directed to the patent invalidation case of Cubist Pharmaceuticals, Inc. confirmed the above item (4) in the Guidelines for Patent Examination and held that, “[T]his kind of (Swiss type) claims binds the making behavior of a manufacturer who makes a drug for a certain use, so the technical features of the claims should be analyzed from the perspective of process claims, … .As for the features only relating to use of a pharmaceutical, such as administration dose, administration interval and the like, if these technical features are not directly related to the procedure of manufacture of the pharmaceutical, they substantially belong to specific courses of administering the pharmaceutical to human body after the procedure of manufacture of the pharmaceutical has been carried out and the pharmaceutical has been obtained, and are not directly and necessarily associated with the procedure of manufacture of pharmaceutical; the technical features merely present in the course of administration are not technical features in the procedure of manufacture of pharmaceutical, and do not have any limiting effect on the procedure of manufacture of pharmaceutical per se”.

In this case, the Supreme Court also held that the pharmaceutical in the sense of the Patent Law is different from the drug in the drug administrative regulation, and “the procedure of manufacture of a pharmaceutical in the sense of the Patent Law usually refers to the act of preparation of a particular pharmaceutical per se through particular steps, processes, conditions, raw materials etc, and does not include such steps as drafting specification, label and package etc. prior to drug packaging and delivery”;
unit dose is an amount of drug in a single unit of drug, which depends on the drug added in the preparation of drug. Administration dose is an amount administered to patients per dose or per day, that is, the amount of use of drug, and can be determined by the users, and belongs to the methods for using drugs. Administration dose does not have a limiting effect on the Swiss type claim unless it can be embodied in the procedure of manufacture of a pharmaceutical; the effect of reducing toxic or side effects does not have a limiting effect on the Swiss type claim if it does not change the patients or indications.

Accordingly, if the technical feature regarding “administration dose” can be embodied in a form of a unit dose, it may be patentable, because unit dose is generally recognized as a technical feature in procedure of manufacture of a pharmaceutical. For example, the technical feature “unit dose is about 0.05-1.0mg” defined in a Swiss-type claim is generally recognized to have limiting effect on the claim.

As for a medical use invention, if the only novel feature lies merely in dosage regimen like in paragraph 17) of the Working Guidelines, for example, in the circumstance where the only novel feature of a known drug to treat a known illness is providing the drug “once per day prior to sleep”, the invention is not patentable due to lack of novelty.

d) What forms of second medical use claims are permissible? See, for example, paragraphs 26) - 33) above/WGLs.

Only Swiss-type use claims are permissible in China, that is, claims in the form of “use of compound X in/for the manufacture of a medicament for the treatment of disease Y”.

e) What forms of second medical use claims are not permissible? See, for example, paragraphs 26) - 33) above/WGLs.

It is prescribed in Article 25.1(3) of the Chinese Patent Law that methods for the diagnosis or for the treatment of diseases shall not be granted patent right. According to the provisions on claims of medical use of substance in the Section 4.5.2 Chapter 10 Part II of the Guidelines for Patent Examination, an application relating to the medical use of a substance shall not be granted if its claim is drafted in the wording “use of substance X for the treatment of diseases”, “use of substance X for diagnosis of disease” or “use of substance X as a medicament”, because such claim is one for “method for diagnosis or for the treatment of diseases” as referred to in Article 25.1(3).

Referring to the paragraphs (26)-(33) in the Working Guidelines, a claim relating
to second medical use cannot be drafted as a claim relating to a method of
treatment of a disease or a product in the following forms:
-- “A use of substance X for treating condition Y”;
-- “A method of treating a patient suffering from disease Y comprising:
administering an effective amount of substance X to the patient”;
-- “Substance X for use in the treatment of condition Y”.

The former two forms are recognized as method for the treatment of diseases.
The last form is recognized as a product claim, and since the use technical
feature “for use in the treatment of condition Y” does not enable the product to
possess novelty, the product claim is not patentable due to lack of novelty.

f) Has any guidance been provided by courts or the national patent office in relation
to the meaning, scope and/or effect of ‘treatment’, ‘treating’ or ‘use to treat’ integers in
second medical use claims? See, for example, paragraphs 34) - 39) above WGLs.

No clear guidance in relation to the meaning, scope and/or effect of “treatment”
in second medical use claims has been provided by courts or the national
patent office (SIPO) in China. In general, the meaning, scope and/or effect of
“treatment” should be judged on the basis of the contents as disclosed in the
specification in combination with the prior art and evidences etc.

As to the methods for the diagnosis or for the treatment of diseases that are
excluded from the protection under Article 25.1(3) of Patent Law, in the
Guidelines for Patent Examination, “methods for the treatment of diseases” has
the definition that “methods of treatment for diseases refer to the processes of
intercepting, relieving, or eliminating the cause or focus of diseases so that the
living human or animal bodies may recover or gain health or relieve pain; and
methods of treatment for diseases include the various methods which serve
treatment purpose or which are of treatment nature; prophylactic methods and
methods of immunization are regarded as methods of treatment for diseases”,
and “methods for the diagnosis of diseases” has a definition that “diagnostic
methods refer to the processes of identifying, studying, and determining the
cause or focus of diseases on living human or animal bodies”. The above
definitions may be referenced by courts or the national patent office to explain
the meaning, scope and/or effect of “treatment” in second medical use claims
in China.

In the procedures of patent prosecution and patent validation, it is generally
required in legal practice in China that the specification of the patent
application must provide experimental evidence to verify the use and/or effect
of the “treatment”. As for a medical use invention, it is explicitly prescribed in
the Guidelines for Patent Examination that if a person skilled in the art is unable,
on the basis of the prior art, to predict that said use or action stated in the
invention can be carried out, the qualitative or quantitative data of the laboratory test (including animal test) or clinical test shall be sufficiently provided for a person skilled in the art to be convinced that the technical solution of the invention can solve the technical problem or achieve the technical effect as expected; and that the circumstance in which the description sets forth a concrete technical solution but without experimental evidence, while the solution can only be established upon confirmation by experimental result is regarded as unable to be carried out due to lack of sufficient disclosure. For example, as for an invention relating to novel use of a known compound, in general, the description is required to provide experimental evidence to validate the new use and effect thereof; otherwise, the invention is regarded as unable to be carried out.

When determining infringement of a second medical use claim, the courts in China are more likely to consider the indications to which the second medical use claim is directed and evidences such as drug information leaflet or other credible publicity materials etc.

As far as determination of infringement is concerned, the technical feature regarding “use to treat” is typically regarded as potential therapeutic use rather than practical treatment act. For example, if the information leaflet of a drug made, sold and offered to sell recites the claimed use of drug, the act of making, selling and offer to sell the drug is regarded as infringing the second medical use claim, no matter whether or not the drug is actually administered to patients.

3) If your country permits second medical use claims:

a) Who may be liable for infringement of such claims? For example:
   i) the party marketing the drug with label instructions which describe the patented use;
   ii) the physician prescribing the drug for such use;
   iii) the pharmacist dispensing a drug for such purpose;
   iv) the patient using the drug for such purpose?

There are limited cases relating to the determination of infringement of second medical use claim in the courts in China, and a recent case is the infringement case wherein Zhengda Tianqing Pharmaceuticals Ltd. and Beijing Yibao Quanxin Large Pharmacy Ltd. were prosecuted by Novartis for infringing the patent right of the use invention patent (i.e., use of Imatinib mesylate for treating gastrointestinal stromal tumors). The two defendants were ordered by Beijing second Intermediate Court to carve out the relevant contents regarding “treatment of gastrointestinal stromal tumors” from the drug information leaflet. The objects ordered in the case are only the parties for making and selling the
infringing drug. Although the infringing drug has entered into the chain of drug administration, the physician prescribing the drug for such use, the pharmacist dispensing the drug for such purpose and the patient using the drug for such purpose were not accused in this case.

It is prescribed in Article 11 of the Patent Law that after the grant of the patent right for an invention, except where otherwise provided for in this Law, no entity or individual may, without the authorization of the patentee, exploit the patent, that is, make, use, offer to sell, sell or import the patented product, or use the patented process, and use, offer to sell, sell or import the product directly obtained by the patented process, for production or business purposes.

A second medical use claim (i.e., claim in the form of “use of compound X in the manufacture of medicament Y”) permitted in China is generally regarded as a process claim. Therefore, the protection scope of second medical use claims seems to be that “no entity or individual may, without the authorization of the patentee, exploit the patent, that is, use the patented process, and use, offer to sell, sell or import the product directly obtained by the patented process, for production or business purposes”.

However, it is prescribed in Article 69 of Patent Law that the circumstance “where for the purposes of providing information needed for the regulatory examination and approval, any person makes, uses or imports a patented medicine or a patented medical apparatus, and where any person makes, imports the patented medicine or the patented medical apparatus exclusively for such person” shall not be deemed as infringement of the patent right.

According to the provisions of the Section 7.2 Chapter 10 Part II of the Guidelines for Patent Examination (2010 Edition), as the prescriptions of a doctor, the making up of a prescription by a doctor and the process of medicine dispensation merely according to the prescription of a doctor do not possess practical applicability, they shall not be granted the patent right. In addition, according to the provisions of the Section 4.3 Chapter 1 Part II of the Guidelines for Patent Examination (2010 Edition), for humanity and ethical reasons, it is acknowledged that a doctor shall be given the freedom to choose any means in the course of diagnosis or treatment of diseases; moreover, this kind of methods are not susceptible of industrial application because they are practiced directly on living human or animal bodies, and are not inventions-creations in the context of the Patent Law; therefore, methods for diagnosis or for treatment of disease shall not be granted patent rights.

Therefore, it is generally regarded that the act of physician prescribing a drug for certain use is not deemed as infringement of the patent right.
In China, pharmacists either are employees of hospital or are employees of pharmacy selling drugs, and the act of pharmacists dispensing a drug for certain purpose generally is not deemed as infringement of the patent right.

Since use of an infringing drug by a patient is not for production or business purposes, the act of patient using the drug for certain purpose is not deemed as infringement of the patent right.

b) Are any parties exempt from infringement or liability for infringement of such claims. If so, what classes of party?

It is prescribed in Article 69 of the Patent Law that none of the following shall be deemed as infringement of the patent right:

(1) where, after the sale of a patented product or a product obtained directly by a patented process by the patentee or any entity or individual authorized by the patentee, any other person uses, offers to sell, sell, or imports that product;

(2) where, before the date of filing of the application for patent, any person who has already made the identical product, used the identical process, or made necessary preparations for its making or using, continues to make or use it within the original scope only;

(3) where any foreign means of transport which temporarily passes through the territory, territorial waters or territorial airspace of China uses the patent concerned, in accordance with any agreement concluded between the country to which the foreign means of transport belongs and China, or in accordance with any international treaty to which both countries are party, or on the basis of the principle of reciprocity, for its own needs, in its devices and installations;

(4) where any person uses the patent concerned solely for the purposes of scientific research and experimentation; or

(5) where for the purposes of providing information needed for the regulatory examination and approval, any person makes, uses or imports a patented medicine or a patented medical apparatus, and where any person makes, imports the patented medicine or the patented medical apparatus exclusively for such person.

It is prescribed in Article 70 of the Patent Law that any person, who, for production and business purpose, uses, offers to sell or sells a patent infringement product, without knowing that it was made and sold without the authorization of the patentee, shall not be liable to compensate for the damage of the patentee if he can prove that he obtains the product from a legitimate channel.
c) Are such claims enforceable on the basis of direct or indirect infringement? Please provide details.

We generally understand that direct infringement is the act of making, using, offering to sell, selling or importing a drug with a package information reciting the second medical use and indications thereof for production and business purpose without the authorization of the patentee.

At present, there is little of direct infringement case in China. In the latest infringement case relating to the invention patent “use of Imatinib mesylate and pharmaceutically acceptable salts thereof for treating gastrointestinal stromal tumors”, the generic manufacturer (Zhengda Tianqing Pharmaceuticals Ltd.) and the seller (Beijing Yibao Quanxin Large Pharmacy Ltd.) of the generic drugs were ordered by Beijing Second Intermediate Court on March 27, 2014 to carve out the relevant contents regarding “treatment of gastrointestinal stromal tumors” in the drug information leaflet.

As for indirect infringement, it is our opinions that it mainly focuses on off-label use and cross-label use (off-label use being the use of an active ingredient for the treatment of a condition other than that for which it has been authorized, and cross-label use being the use of a generic medicine for a condition carved out or even expressly disclaimed by the generic manufacturer but which was included on the originator’s product information leaflet or other regulatory data). Since there is no judicial practice in China for off-label use and cross-label use, we cannot provide details for indirect infringement.

By the way, there is no such practice as “indirect infringement”, but there is the practice of “contributory infringement” in China. Under Article 8 of the Tort Law, where two or more persons jointly commit a tort, causing harm to another person, they shall be liable jointly and severally. Under Article 9, one who abets or assists another person in committing a tort shall be liable jointly and severally with the tortfeasor.

4) If a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, is it an infringement if a party makes, supplies or uses a generic version of the drug for any use?

If it can directly or indirectly be found from package information of a generic version of the drug made, supplied or used by a party that one or more uses of the generic version fall within the claims of a patent, it is deemed as infringement. However, in general, the generic pharmaceutical company is not obligated to take action to prevent other person from applying the generic drug in the claimed medical uses.
5) If the answer to Question 4) is yes, please answer the following sub questions in that context.

a) Is each of the acts of making, supplying and using a form of infringement? If not, please specify which (or any other) acts which constitute infringement.

Each of the acts of making and supplying a generic drug wherein indication(s) specified in the drug specification or information leaflet falls within the claims of a patent constitutes infringement.

When the product information leaflet of the generic product does not include any reference to the patented second medical use, which mainly involves off-label use and cross-label use, infringement may be determined based on other publicity materials and would be hard to be determined if publicity materials do not describe the patented second medical use.

Infringement determination of off-label use and cross-label use also depends on the interpretation of Swiss type use claims. On one hand, it seems that some courts of China interpret Swiss-type second medical use claims (“use of compound X in a preparation of a medicament for treating a disease Y” permitted in China) as a process for preparing a medicine by use of compound X. For example, the Beijing High Court held in the final decision of a patent invalidation case against Merck Co (Administrative Judgment (2008) GaoXingZhongZi No. 378, Beijing High Court) that “claims to medical use inventions usually comprise the drug substance feature, drug preparation feature and indication feature”, and “acts not involving drug preparation” will not infringe the patent right. In addition, the Supreme Court held in the Retrial Ruling associated with Cubist Pharmaceuticals, Inc. (see Administrative Ruling (2012) ZhiXingZhongZi No.75) that, “This kind of (Swiss type) claims binds the making behavior of a manufacturer who makes a drug for a certain use”. On the other hand, it is explicitly described in the Chapter of Some Provisions on Examination of Invention Applications in the Field of Chemistry in the Guidelines for Patent Examination (2010 Edition) that “[T]he invention relating to the use of a chemical product is made on the basis of discovery of a new property of the product and the use of such property”. Therefore, perhaps, it may be considered that the drafting format of Swiss type claims is for circumventing the exclusion from patentability in the Patent Law that the treatment methods like “Substance X for use of treating condition Y” are unpatentable subject matter, and the essence of Swiss type use claims lies in medical use of Substance X. Therefore, it may be considered that the determination of infringement for Swiss type use claim does not require the procedure of drug preparation as essential elements.
In addition, with regard to off-label use and cross-label use, the following factors should be considered.

**Definition**

--“Off-label use”

“Off-label use” is where a medicine is used for a non-approved indication. For instance, a compound is authorized for A and B but the compound is used for an unrelated condition C.

-- “Cross-label use”

“Cross-label use” means the use of a generic medicine for a condition carved out or even expressly disclaimed by the generic manufacturer but which was included on the originator’s product information leaflet or other regulatory data. For instance, an innovator’s medicine has a label for a non-patented indication (A) and a patented indication (B). A generics company obtains an approval for a generic version of the medicine but only for indication (A). This is called a “skinny label”. If the generic medicine is used for patented indication B, this is “cross-label” use.

**The related Regulatory Scheme**

There is a regulatory scheme in the Chinese drug management regulations.

--Prescription drugs can only be sold for the indications included on the label which must be approved by the China Food and Drug Administration.

--China has a standard form for prescription drugs, and there is a “diagnosis” section on the standard prescription form.

--In prescribing drugs, doctors must fill out all sections of the standard prescription, including the “diagnosis” section. Moreover, doctors can only prescribe drugs for the indications included on the label.

--In dispensing prescription drugs, pharmacists are required to check if the prescribed indication is consistent with the clinical diagnosis.

--Reimbursement for a medicine is generally based on its chemical name, although some brand names are used. Moreover, reimbursement typically is NOT based on indication, although some provinces may make such a distinction among various indications.
Liabilities, penalties and/or fines can attach to a violation of any of the above regulatory requirements.

According to the regulatory scheme, “off-label use” and “cross-label use” are prohibited in the prescription management regulation and other related regulations.

Due to the regulatory scheme, “cross-label use” may occur in self pay patients, insured patients, physicians and pharmacists. With respect to “cross label use” by self pay patients, there is not much that innovator companies can do in terms of legal and regulatory relief. However, physicians and pharmacists can incur various liabilities, penalties, and fines when they engage in cross-label of a medicine.

In addition, based on the different interpretations for Swiss type use claim as above and the specific infringement behavior, “cross-label use” may infringe the patented use. For example, it is thought by some people that “cross-label use” by a generic pharmaceutical company may infringe the patented second medical use.

In conclusion, in China, “cross-label use” by a generic company may constitute patent infringement; physicians and pharmacists can incur various liabilities, penalties, and fines when they engage in cross-label of a medicine; thus, cross-label use by generic companies would face difficult legal and regulatory hurdles; and cross-label use would happen due to patient’s own behavior and moreover it may also happen if there is a violation of the relevant regulations. However, currently, there is no clear provision or legal practice with regard to these issues in China.

b) Is it necessary for a finding of infringement that the party making, supplying or using the generic version of the drug does so in connection with the infringing use?

Yes, it is necessary. When the act of making or supplying generic version of the drug per se is not in connection with the infringing use, the act does not constitute infringement. However, the use is unnecessary to practically occur, for example, treatment act is unnecessary to actually occur.

c) If yes to b), is it necessary that the party knows that their actions are in connection with the infringing use?

It is unnecessary, because the act constitutes direct infringement.

d) If yes to c), what standard of knowledge is required? See, for example, paragraphs 38) and 47) above.
6) How do the courts determine infringement of a second medical use claim? What are the legal tests and evidentiary requirements?

In the limited existing cases, the courts mainly consult a package material of a suspected infringing generic drug. For example, the drug specification is considered as main proof. However, the following circumstance may not be excluded, i.e., although the package material of a generic drug does not expressly indicate the second medical use of a patent, other evidences (such as the publicity materials of a manufacturer making the generic drug) recite or expressly indicate the claimed second medical use, the courts might determine that the manufacturer of making the generic drug constitutes infringement.

7) What relief is available for infringement of a second medical use claim:

a) at a preliminary / interim / interlocutory level?

b) by way of final relief?

No special provisions on relief are explicitly made for the infringement of a second medical use claim in Chinese Laws. However, it is believed that relief measures for normal infringement can be taken, for example a) at a preliminary/interim/interlocutory level and b) by way of final relief.

Specifically, according to Articles 100 and 101 of the Civil Procedure Law (amended 2012) and Article 66 of the Patent Law, where any patentee or interested party has evidence to prove that another person is infringing or will soon infringe its or his patent right and that if such infringing act is not checked or prevented from occurring in time, it becomes impossible or difficult to enforce a judgment or it is likely to cause irreparable harm to it or him, it or he may, before any legal proceedings are instituted, petition the people’s court to adopt measures to stop the relevant acts.

In addition, according to Article 81 of the Civil Procedure Law (amended 2012) and Article 67 of the Patent Law, in order to stop patent infringement, under the circumstances where the evidence might be destroyed or where it would be difficult to obtain in the future, the patentee or the interested party may petition the people's court for evidence preservation before instituting legal proceedings.

8) In respect of Question 7)a), can a preliminary / interim / interlocutory injunction be granted solely upon the statements provided in the product packaging or based on the writing of a prescription? If not, what is the basis for relief?
In practice, the conditions for granting preliminary injunction in patent infringement litigation are that the petitioner is the patentee or interested party, the patent right is relatively stable, the respondent is infringing or will soon infringe its or his patent right, the circumstance is urgent and it is likely to cause irreparable harm to it or him if the infringing act is not checked or prevented from occurring in time, and the petitioner shall provide a security. The statements provided in the product package materials can only prove the infringement.

9) In respect of Question 7)b), what level of proof is required to obtain a final injunction?

When the patent right is valid, if the act of making a generic drug can be determined as infringement according to the above item 6), a final injunction should be obtainable. But the grant of the final injunction should also consider whether it is contrary to public interest and whether the stop of the relevant acts may cause any significant imbalance of interests between the parties concerned.

II. Policy considerations and proposals for improvements to your current law

10) If your country permits second medical use claims, please answer the following sub questions.

a) What are the policy reasons behind permitting such claims?

Second medical use claims have been permitted since 1993 in China (see, the Guidelines for Patent Examination, 1993 edition), whereby more research and development technicians are encouraged to step into researches on second therapeutic use of a known drug. In addition, since pharmacological activity and toxic and side effects of a known drug when firstly used are not sufficiently and thoroughly learnt, there is possible potential medication unsafety. With the development of second use of the drug, medication safety will be established more sufficiently and thoroughly, and it will benefit patient's health. In view of encouragement of inventions-creations and the healthy interests of patients, second medical use claims are permitted in China.

b) Are such claims as are currently permissible in your country considered to strike the right balance between the interests of relevant stakeholders?

It should be considered to strike the right balance among originator pharmaceutical companies, generic pharmaceutical companies and patients (or the public).
c) Is it considered that such claims better serve the interests of some stakeholders and/or are detrimental to other stakeholders?

In China, the patent right protection/enforcement of such claims are merely in making and selling chains, and do not relate to administration chain by physicians, pharmacists and patients. Moreover, infringement is determined on the basis of the package materials of drug or other possible publicity materials, and the patentee can only enforce the patent rights to some extent.

d) If there is any empirical or anecdotal data available, please address the following.

i) What is the prevalence of second medical use claims in your country?
ii) What is the profile of patentees for second medical use claims in your country?

Since there is little of such cases in China, there is not any empirical or anecdotal data available.

11) If your country does not permit second medical use claims, please answer the following sub questions.

a) What are the policy reasons behind not permitting such claims?

b) Would such claims serve the interests of relevant stakeholders?

c) Would such claims be considered to better serve the interests of some stakeholders and/or be detrimental to other stakeholders?

12) To what extent does your country's law in relation to second medical use claims affect the pharmaceutical industry (originator and generic) in your country?

According to the provisions of Article 69(5) of the Patent Law and the Bolar exception clauses of the pharmaceutical administration regulations in the China Food and Drug Administration, generic drugs relating to second medical use are permitted to enter into the stage of regulatory examination and approval, but are not permitted to enter into the stage of marketing before the expiration of the second medical use patent.

III. Proposals for harmonisation

The Groups are invited to put forward proposals for the adoption of harmonised laws in relation to second medical use claims. More specifically, the Groups are invited to answer the following questions without regard to their existing national laws.
13) Is it desirable to permit second medical use claims?

It is desirable to permit second medical use claims. In fact, second medical use claims have been permitted in China.

14) Is harmonisation of laws relating to second medical use claims desirable?

In this regard, different stakeholders have different opinions. For example, someone deems that it should not place undue emphasis on harmonisation of laws relating to second medical use claims without considering practical demands in different countries. However, legal practice in different countries has reference value to one another.

15) Please provide a standard that you consider to be best in each of the following areas relating to second medical use claims.

a) Types of second medical use constituting permissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

With the development of pharmaceutical industry in China, it may be desirable that the types of second medical use constituting permissible subject matter in China will be extended to the scope prescribed in EPC2000.

b) Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

With the development of pharmaceutical industry in China, it may be desirable that the types of any second medical use constituting impermissible subject matter in China will be consistent with those in EPC2000.

c) Form of permissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

With the development of pharmaceutical industry in China, it may be desirable that the form of permissible claims in China is consistent with that in EPC2000.

d) Form of impermissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

With the development of pharmaceutical industry in China, it may be desirable that the form of impermissible claims in China is consistent with that in EPC2000.

e) Who may be liable for infringement?
In China, a manufacturer making a generic drug and seller are liable for infringement at present. If the types of second medical use constituting permissible subject matter in China are extended to be consistent with those in EPC2000, more infringers may be determined by reference to practice of patent right protection in Europe.

f) Any parties/institutions that should be exempted from infringement or liability for infringement.

Physicians, pharmacists and patients should be exempted from infringement or liability for infringement.

g) Where a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, the acts that should constitute patent infringement, and in particular, the standard of knowledge of the alleged infringer.

If the act of making or supplying a generic drug is in connection with indications covered by the claims of a patent, it will constitute infringement. As to direct infringement, the knowledge of the alleged infringer is not required to be considered.

h) Relief available upon a finding of infringement:

i) at a preliminary / interim / interlocutory level; and

ii) by way of permanent relief.

Both i) and ii) are available.

i) In each case for h)i) and h)ii), the level of proof for the granting of such relief.

In case for h)i), the petitioner needs to prove that the petitioner is the patentee or interested party, the patent right is relatively stable, the respondent is infringing or will soon infringe its or his patent right, the circumstance is urgent and it is likely to cause irreparable harm to it or him if the infringing act is not checked or prevented from occurring in time, and the petitioner shall provide a security.

In case for h)ii), usually it is sufficient to prove that the act constitutes infringement. But other factors should also be considered such as whether the stop of the relevant acts is contrary to public interest or may cause any significant imbalance of interests between the parties concerned.
Summary

The only claim type allowable in China for a second medical use invention is the Swiss type claim. The features merely present in the course of administration do not confer novelty on the Swiss type claim.

There is little judicial decision on how to assess infringement of a Swiss type claim. It is generally believed that the Swiss type claim is enforceable mainly on the basis of direct infringement in cases where the product information leaflet of the generic product includes reference to the patented use. Any parties making, offering to sell, selling or importing a drug with label instructions which describe the patented use for production and business purpose are liable for infringement of such claims, but physicians, pharmacists and patients are believed to be exempt from infringement. Preliminary and interim injunction and final relief are available for infringement of a second medical use claim.