PAKISTAN

The Patents (Amendment) Ordinance 2002, which was promulgated on 26 October 2002, has made some very significant amendments in the Patents Ordinance 2000 (which came into force on 2 December 2000 and repealed and replaced the Patents and Designs Act 1911), which amendments are not in conformity with Pakistan's treaty obligations under TRIPs and the Paris Convention and generally accepted concepts of patent law and will have serious and far reaching and detrimental consequences particularly for the pharmaceutical industry. A brief summary of the significant amendments and their effect are set out below. Also set out below are a few issues relating to the Patents Ordinance 2000 which require reconsideration as they do not conform to Pakistan's obligations under TRIPs and the Paris Convention.

Summary

- Well established and internationally accepted principle of Group of Inventions/Unity of Inventions excluded [sections 13(3), 15(2A), 15(8)]

- Separate applications required for each derivate and salt of a chemical product intended for use in agriculture or medicine [sections 13(3), 15(2A), 15(8)]

- Biological products per se cannot be patented – both process and product must be novel [sections 2(s), 7(4)(d), 15(8)]

- Novel process for preparing admixtures not patentable [proviso to section 15(8)]

- Scope of expression "industrial application" restricted – full effect not given to Article 1 of the Paris Convention and Article 27 of TRIPs [Section 10]

- Exclusive marketing rights for local patents – beyond the scope of Articles 70(9) of TRIPs [Section 13(9), 30(4), 30(4A) 105(2)]

- Parallel imports allowed [Section 30(5)(e)]

- Bolar Exception: permits third parties to take actions necessary for seeking approval of a product for its commercialization – but no time limit prescribed for this [Section 30(5)(e)]

- New or subsequent use of a known product or process prohibited [section 7(4)(d)]

- State of the art: disclosure of an invention in breach of confidence and unlawful disclosure is no longer protected [section 8(3)]

- Revocation of patent: by Federal Government without judicial review – contrary to Article 32 of TRIPs [section 48].

- Revocation of patent: by Federal Government for concealment or misrepresentation – matters which should be left to be dealt with by parties inter se [section 48]

- Revocation of patent: by Federal Government where compulsory licensing not adequate – contrary to Article 31 of TRIPs and Article 5A of the Paris Convention [section 48]

- Compulsory Licensing: grant by Federal Government at any time – does not conform to Article 5A(4) of the Paris Convention – no licence within 3 years of grant of patent [section 58]

- Non-Voluntary Licensing: grant by the Controller to prevent abuse – abuse not defined – also failure to work no longer qualified and may be limited to local manufacture – contrary to Article 27(1) of TRIPs and Article 5A(1) of the Paris Convention [section 59]

- List of relief Court may grant: Court's powers limited to reliefs specified – no provision for other relief which Court considers necessary or desirable – will impair enforcement of rights [Section 61]

- Term of patent: patents in force on 1 January 1995 when TRIPs became applicable to Pakistan and those granted subsequent to that date must have a term of 20 years – no provision made in this regard [section 31]

Group of Inventions : Sections 13(3), 15(2A) and 15(8)

It is generally accepted practice that a group of inventions which are cognate or so related as to constitute one invention or where one invention is a modification of another, may be included in a single application for the grant of a patent. So for example a specification which claims the manufacture of one class of compounds and includes separate claims for the process of manufacture and also for the products obtained may be included in a single application.

Also, a specification which describes a chemical manufacture taking place in two or more stages, involving the production of one or more group of intermediate products which are distinct in character from the product, then a single application may claim a patent for the final products and also the intermediate products (provided the intermediate products are novel per se or if not novel are produced in a novel way – however in the past in Pakistan there was no requirement to establish novelty of intermediates or to establish that the process to produce the intermediate was novel). Whether a group of inventions are so related as to be included in a single application or whether there is a plurality of inventions which ought to form the subject matter of separate applications, is a matter to be decided in each case on the basis of the invention disclosed in the specification and the claims made. Patent Offices are accustomed to making such decisions. If the Patent Office is of the view that there is a plurality of inventions which should form the subject matter of separate applications,

then the applicant is asked to divide out his patent application, that is, to file divisional application, one each for the separate groups of inventions.

The Patents Ordinance 2000 (as amended) as also the repealed Patents and Designs Act 1911 and the Paris Convention (and also TRIPs by reference to the Paris Convention) provide for the filing of divisional applications.

Section 13(3), which is a provision of general application and applies to all inventions and not only to those relating to the pharmaceutical industry, has been amended as follows:

(3) Each application shall relate to one invention only ~~or to a group of inventions so linked as to form a single general invention concept~~.

Thus, groups of inventions have been specifically excluded and separate applications will have to be filed for each intermediate and the final product and to the extent required also the process of manufacture. This is contrary to established and generally accepted practice worldwide.

As regards patent applications for pharmaceutical and agricultural products, it is likely that the Patent Office in Pakistan may on the basis of the recent amendment in section 13(3) of the Patents Ordinance 2000 raise objections where the patent application includes claims for not only the principal active ingredient but also for salts thereof. In the past in Pakistan a general claim for salts of an active ingredient in the application for the grant of a patent in respect of that ingredient without specifying the particular salts has been acceptable but this may no longer be the case. However, in the event of such an objection being raised, it could be contended that the principal active ingredient and the salts thereof are in fact a single invention as the process for the production of the active ingredient and of the salts is the same and that the process for the production of the salt is part and parcel of the process claim or an extension thereof. If the Patent Office does not accept this argument (which is yet to be tested), the applicant may have to file a divisional application for each salt claimed.

The above argument, however, is not available in the case of a black box (mail box) application, that is an application for the grant of a patent in respect of the product intended for use in medicine or agriculture which will be examined after 31 December 2004, in view of the new sub-sections (2A) and (8) introduced in section 15 of the Patents Ordinance 2000 by the Patents (Amendment) Ordinance 2002. These new sub-sections provide as follows:

(2A) For a chemical product intended for use in medicine or agriculture, the specification shall be specific to one chemical product only describing the physical, chemical, pharmacological and pharmaceutical properties or, as the case may be, the properties related to its use in agriculture and its impact on environment.

(8) Claim or claims in respect of a complete specification of a chemical product intended for use in agriculture or medicine shall be structurally defined and shall relate to a single chemical product only, excluding its derivates and salts, each of which, with a material or a novel improvement in its claim from the main product, shall be filed as a separate invention or where applicable as a divisional application. Where structural description is not possible, as in

the case of biological products, the "product by process" claim shall be made and protection shall be limited to the product obtained with the claimed process only:
Provided that a claim which is based on a mere admixture resulting only in aggregation of the properties of the component substances thereof, or a processing of producing such substance, shall not be allowed.

As a consequence of the amendments made, patent applications for pharmaceutical products will have to be limited to the active ingredient and separate applications will have to be filed for each salt separately for which protection is additionally required.

Biological Products : Sections 2(s), 7(4)(d) and 15(8)

The new sub-section (8) of section 15 of the Patents Ordinance also provides that in the case of chemical products, such as biological products, for which it is not possible to provide a structural description of the product, the biological product cannot be claimed per se and must be claimed along with the process by which such biological product is made. Thus, not only the biological product but also the process by which it is made must be novel. Further, the sub-section provides that the patent protection is available for the biological product only if made by the process claimed.

In the past in Pakistan it would have been possible to obtain a patent for a new biological product which is produced through a known process. However in view of the revised definitions of "process" in section 2(s) and the new clause (d) introduced in section 7(4) of the Patents Ordinance 2000, it would appear that if the new biological product is manufactured through a known process no patent rights may be granted in respect of such biological product. Section 2(s) as amended and clause (d) of section 7(4) provides as follows:

Section 2(s) : "process" means any art, process or method or manner of new manufacture of a product ~~and includes a new use of any process or a product~~
Section 7(4) : A patent shall not be granted –
(d) for a new or subsequent use of a known product or process

Process of Producing Admixtures : Proviso to Section 15(8)

While admixtures were and are not per se patentable, the proviso to the new sub-section (8) of section 15 also provides that the process for the production of admixtures are not patentable. Thus, it would appear that even if such process is novel no patent will be granted for the process. This clearly violates the treaty obligations.

Industrial Application : Section 10

Section 10 of the Patents Ordinance 2000 has been amended as follows:
Industrial application.- *(1) ~~Subject to sub-section (2),~~ An invention shall be considered to be capable of industrial application if it ~~can be made or used in any kind of industry. The industry shall be understood in its broadest sense. It shall cover in particular agriculture, handicraft, fishery and services~~. is capable of being manufactured or otherwise industrially used.*
~~(2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body shall not be taken to be capable of industrial application:~~
~~Provided that a product consisting of a substance or composition shall not be prevented from being treated as capable of industrial application merely because it was invented for use in such a method."~~

There is some concern that the term “industrially used” may eliminate inventions, whether a product or a process, which may be used in agriculture, handicrafts, fishery, services and other activities which may not in their ordinary sense be classified as an industry, although insofar as a product is manufactured it could be contended that the earlier part of the revised section 10 would allow the product to be patented since it is “capable of being manufactured”.

Further, the section as originally framed was in conformity with the requirements of Article 1 of the Paris Convention and ought therefore to be restored.

Exclusive Marketing Rights : Sections 13(9), 30(4), 30(4A) and 105(2)(xviii)

Applications for the grant of exclusive marketing approval is now required to be filed with the Controller of Patents and not the Ministry of Health, Government of Pakistan, and the Federal Government may frame rules for the procedures to be followed for the grant of such approval. This follows from the new sub-section (9) of section 13 and the reworded sub-section (4) of section 30 and the new clause (xviii) inserted in sub-section (2) of section 105 as follows:

Section 13(9) : An application for availing exclusive marketing rights for a patentable invention relating to pharmaceutical or agricultural chemical product shall be filed in the mailbox provided for this purpose by the Controller who may require the form and manner for submitting such application as may be prescribed.

Section 30(4) : Where a person has filed an application in the mail box, in accordance with sub-section (9) of section 13, for protection of an invention relating to a pharmaceutical or agriculture chemical product, ~~intended for use in medicine or agriculture and has obtained a marketing approval therefore, in another convention country, he shall be entitled to an~~ exclusive ~~privilege for~~ marketing rights shall be granted ~~the said product~~ for a period of five years after obtaining marketing approval ~~of the Ministry of Health, Government of Pakistan,~~ or until ~~the,~~ a product patent ~~on the application~~ is granted or rejected which ever period is shorter, provided that, subsequent to the first January, 1995, a patent application has been filed and a patent granted for that product in any Convention country and marketing approval obtained in such country;

Section 105(2) : (xviii) the form of filing application and manner of grant of exclusive marketing rights.

The reworded sub-section (4) of section 30 would appear to conform to the requirements of Article 70(1) of TRIPs. However the reasons for and the scope of the new sub-section (4A) inserted in section 30 is not clear. Also, there is a concern that the provisions of this sub-section may be misused. Section 30(4A) provides as follows:

(4A) where a person has made an invention in Pakistan in respect of a process of manufacture of any of the products referred to in sub-section (4) and has obtained a patent for the same and has filed an application in the mailbox for protection of the invention, and has been granted marketing approval thereof, then he shall have the exclusive marketing rights for that product for a period of five years after obtaining marketing approval or until a product patent is granted or rejected whichever period is shorter.

Firstly, section 30(4A) is beyond the requirement of TRIPs. Article 70(9) of TRIPs is a transitional arrangement and was introduced to deal with mailbox applications, which are applications filed for patents in respect of chemical products intended for use in agriculture and medicines, which will not be examined by the Patent Office until after 31 December 2004. If allowed an applicant for the grant of a patent in respect of a chemical product per se, where the chemical product is intended for use in agriculture

or medicines and who already has in another country which is a member of the World Trade Organisation a patent in respect of such product and who has also been granted approval by such other member country to market that product in that other member country, to apply for and be granted an exclusive marketing approval in the member country in which the mailbox application has been filed and is pending. The purpose of this article 70(9) of TRIPs is to remove the disadvantages which exist due to the laws of a member country not providing for the grant of patents in respect of products per se but accepting mailbox applications for the grant of such patents for examination after 31 December 2004.

As regards local inventions, since Pakistan has deferred the consideration and grant of patents for chemical products intended for use in agriculture or medicines until after 31 December 2004, there is no question of any exclusive rights being granted to the mailbox applicant of such product if he has secured a patent for the process of manufacture. Furthermore, it is possible that the process patent would amount to prior publication insofar as concerns the mailbox application, since the process patent would certainly disclose the product manufactured by such process.

Parallel Imports : Section 30(5)(a)

The amendments made in clause (a) of sub-section (5) of section 30 now clearly permits parallel import of goods. The amendments made are as follows:

Section 30(5) : The rights under the patent shall not extend to –
(a) acts in respect of articles which have been put on the market any where in the world by the owner of the patent or with his consent or by an authorised person or in any other legitimate manner such as compulsory licenses

Thus the import in Pakistan of products manufactured by the owner of the patent or his licensee in any part of the world does not amount to an infringement of the patent. The following quote from conclusion in the Policy Statement issued by the International Chamber of Commerce on Exhaustion of Intellectual Property Rights (7 January 2000) [that is, parallel imports] explains why parallel imports should be discouraged.

The issue of the exhaustion of rights is very complex. It affects businesses in different ways and to different degrees depending on their sector of activity, the market conditions in which they function, and the geographical region in which they operate.

The great majority of ICC members believe that, in the absence of a true single global market, a regime of international exhaustion would on balance be more harmful than beneficial to international trade and investment, and to innovation. Businesses have a legitimate interest – for reasons relating to commercial strategy, quality control, brand reputation, safety etc – in controlling the distribution of their goods across different markets, to ensure that products tailored for one market are not sold in another. There are also strong arguments that consumers would not necessarily be better off under a regime of international exhaustion.

Bolar Exception : Section 30(5)(e)

The new clause (e) inserted in section 30(5) provides as follows:

Section 30(5) : The rights under the patent shall not extent to -

(e) acts, including tests, necessary for the approval of a product for its commercialisation after the expiration of the patent.

No time period has been specified in section 30(5)(e) of the new clause. Thus, a third party could commence testing very early on in the term of the patent with impurity. This is likely to lead to misuse. While it could be argued that the expression "necessary" would effectively prohibit the manufacture by third parties of the patented product early in the term of the patent, any litigation to restrain such use and involving an interpretation of the provisions of this new clause will, in view of the conditions prevailing in the courts in Pakistan, take anything up to 10 to 15 years to result in a final and conclusive decision. Also there could be multiple litigations as each third party starts in a different year of the term of the patent.

New or subsequent use prohibited : Section 7(4)(d)

A new clause (d) has been inserted in section 7(4) which provides as follows:

Section 7(4) : A patent shall not be granted -
(d) for a new or subsequent use of a known product or process.

Patentability of a new or subsequent use of a known product or process facilitates research and development of secondary uses, which is beneficial and ought to be encouraged. Furthermore, the clause excludes new or subsequent use of a known process which results in a new product. This clearly contravenes both TRIPs and the Paris Convention. An exception to the effect exists in the Indian Patents Act 1970 in section 3(d) thereof as follows:

"The following are not inventions within the meaning of this Act,-
……..
(d) the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
……."

State of the Art : Section 8(3)

The entire sub-section (3) of section 8 has been substituted which reads as follows:

Old Section 8(3): For the purposes of this section, the disclosure of matter constituting an invention shall be disregarded if made within one year immediately preceding the date of filing the application for the patent and either-
(a) the disclosure was due to, or made in consequence of, the matter having been obtained unlawfully or in breach of confidence by a person; or
(b) the disclosure was due to, or made in consequence of, the inventor displaying the invention at any international or official exhibition.
New Section 8(3): Notwithstanding the provisions of sub-section (2), disclosure of a patentable invention in respect of goods shall not constitute 'state of the art' if an article is exhibited at an official or officially recognized international exhibition within twelve months preceding the date of filing of an application for grant of patent. If later on, the right of priority is invoked, then the period shall start from the date of introduction of the article into the exhibition. The Controller may require proof, with such documentary evidence as considered necessary, of the identity of the article exhibited and the date of its introduction into the exhibition.

As a consequence, disclosure by a person of an invention in breach of his obligation to keep the invention confidential or by a person who has obtained the invention unlawfully, is no longer protected and any such disclosure would be fatal to the application for the grant of a patent in respect of such invention filed subsequent to such disclosure.

Revocation of patent : Section 48

Section 48 has been substituted which provides as follows:

Section 48 : Where the Federal Government is of opinion that-
(a) a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public; or
(b) a patent has been obtained through concealment or misrepresentation in the application; or
(c) where the compulsory licence granted to prevent the abuse which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work or in relation to anti-competitive practices, has not been sufficient, it may, after giving the patentee an opportunity of being heard, make a declaration to that effect in the official Gazette, and thereupon the patent shall be deemed to have been revoked:
it may, after giving the patentee an opportunity of being heard, make a declaration to that effect in the official Gazette and thereupon the patent shall be deemed to have been revoked.

It is not clear why two new grounds of revocation have been included in section 48 of the Patents Ordinance 2000. Neither of these grounds are appropriate. If there has been any concealment or misrepresentation in an application for the grant of a patent, then a person whose rights are affected by the grant of the patent may apply under section 46 of the Patents Ordinance 2000 for the revocation of the patent on the ground that the grant of the patent but for the fact concealed or misrepresented ought to have been refused. The concern here is that the provisions of clause (b) of section 48 may be open to misuse. The revocation is by the Federal Government giving notice in the Official Gazette and not through a judicial court process, although that is possible under section 46 of the Patents Ordinance. Furthermore, clause (b) of section 48 is contrary to the provisions of Article 32 of TRIPs.

As regards new clause (c) inserted in section 48, this clause is wholly inappropriate. Under TRIPs and the Paris Convention a patentee's rights cannot be taken away except through a compulsory licence granted on the grounds and subject to the conditions set out in Article 31 of TRIPs and Article 5A of the Paris Convention. It is only where the Federal Government is of the opinion that a compulsory licencing would not prevent the abuse that revocation of the patent may be considered as an option. If the Federal Government has taken the view that a compulsory licence ought to be granted, then there cannot be any ground to revoke the patent. Further, as mentioned above, the power to revoke should be exercised through the courts in accordance with the provisions of Article 32 of TRIPs.

Compulsory Licences : Sections 58 and 59

Two new sub-clauses have been inserted in section 58(1) which read as follows:
Section 58(1) : (iii) the patent holder refuses to grant a licence to a third party on reasonable commercial terms and conditions; or

(iv) where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology.

Two new circumstances have been included in section 58(1) of the Patents Ordinances in which the Federal Government may grant a compulsory licence to a government or agency or a third party. These two new circumstances reflect the provisions of Article 31(b) and Article 7 of TRIPs. However, the provisions of section 58 fail to prescribe the period after the filing of an application for the grant of a patent or after the patent has been granted after which the powers to grant compulsory licences under section 58 may be exercised. This period is prescribed in Article 5A(4) of the Paris Convention and is also reflect in section 59 of the Patents Ordinance 2000 with respect to voluntary licences but does not extend to compulsory licences under section 58.

Further, the amendments made in sub-section (1) of section 59 of the Patents Ordinance 2000 is likely to result in confusion. This sub-section has been reworded as follows:

Section 59(1) : On request, made to the Controller after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the Controller may issue a non-voluntary license to prevent the abuses which might result from the exercise of the rights conferred by the patent, for example, failure to work.

The term "abuse" is not defined except to the extent of the example quoted in that sub-section, that is, "failure to work". Presumably, failure to work, means failure to work the patent anywhere in the world and not simply in Pakistan. Originally, this sub-section clearly stated that an patent may be considered as being worked so long as the patented products were available in Pakistan. By virtue of the provisions of Article 27(1) of TRIPs and Article 5A(1) of the Paris Convention the importation of a patented product would be considered as working the patent.

Reliefs in suits for infringement : Section 61

A new sub-section (1) has been substituted for the original sub-section. The original sub-section contained an elaborate list of the reliefs which may be granted by the Court in any suit for infringement. This list has now been reduced to just two clauses as follows:

Old section 61(1) In any suit for infringement the Court shall have the power-
(i) to order to desist from infringement;
(ii) to prevent the entry into the channels of commerce of imported goods that involve the infringement immediately after custom clearance of such goods;
(iii) to order the infringer to pay to the right holder damages adequate to compensate for the injury he has suffered because of infringement;
(iv) to pay the right holder expenses which may include appropriate attorney's fee;
(v) in appropriate cases, to order recovery of profits, damages and pre-established damages even where the infringer did not knowingly or with reasonable ground to know, engage in infringing;
(vi) to order that goods found to be infringing be, without compensation of any sought, disposed off outside the channels of commerce;
(vii) to order that material and implements the predominant use of which has been in the creating of infringing goods be, without compensation of any sought, disposed off outside the channels of commerce in such a manner as to

minimize risk of further infringement, and in considering such orders, the need for proportionality between seriousness of infringement and remedies ordered as well as interests of third parties shall be taken into account;
(viii) unless this would be out of proportion to the seriousness of infringement, to order infringer to inform the right holder of the identity of third parties involved in production and distribution of the infringing goods and of their channels of commerce; and
(ix) to order a party at whose request measures were taken and who has abused enforcement procedure, to provide to a party wrongfully enjoined or restrained, adequate compensation for injury suffered because of such abuse; and
(x) to order the applicant to pay the defendant expenses, which may include appropriate attorney's fee.
New Section 61(1) In any suit for infringement the Court shall have the power-
(a) to grant relief by way of damages, injunctions or accounts provided that, where permitted, effective provisional measure may also be ordered by the Court;
(b) to order, if the subject matter of a patent is a process for obtaining a product, the defendant to prove that the process to obtain an identical product is different from the patented process and that the identical product in question shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process provided that the product obtained by patented process is new if it has not been put into the market for more than one year before the date of the initiation of the judicial action by the patentee:
Provided that this provision shall apply subject to the prior proof by the plaintiff that the allegedly infringing product is identical to the product directly produced by the patented process:
Provided further that in the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account

As a consequence of the amendments it may be argued that the powers of the courts in granting reliefs are now limited to damages, injunctions and accounts, although this was surely not the intent. It would therefore be desirable to provide that the court may grant such other relif in the circumstances as it may think fit. Such a provision would permit the court to pass appropriate orders to enforce intellectual property rights.

Term of Patents : Sections 31 and 106(4)

While section 31 of the Patents Ordinance 2000 provides that a patent will be granted for a term of 20 years, this applies only to patents granted after the promulgation of the Patents Ordinance 2000, that is, after 2 December 2000. However, by virtue of the provisions of Article 70(2) of TRIPs, all patents in force on the date of application of TRIPs to Pakistan must have a term of 20 years. Thus, all patents in force on 1 January 1995 and those granted between 1 January 1995 and 2 December 2000 are required to have a term of 20 years. This interpretation of Articles 33 and 70(2) of TRIPs is supported by a WTO Dispute Panel Decision (WT/DS170/R) given in May 2000 and by an Appellate Body Decision (WT/DS170/AB/R) given in September 2000 in a dispute between the United States of America and Canada.

This report is provided by Anwer Ghani of Vellani & Vellani located in Korachi, Pakistan