Drug Patents

An Analysis of Pakistan's Patent Law

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Hafiz Aziz ur Rehman

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Author: Hafiz Aziz ur Rehman

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40-A Ramzan Plaza, G-9 Markaz, Islamabad, PAKISTAN
e-mail: main@thenetwork.org.pk
websites: www.thenetwork.org.pk
www.thenetwork.org.pk

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Introduction

Patents have been one of the most hotly debated topics on access to essential medicines since the creation of the World Trade Organization (WTO) and the conclusion of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1994. Patents are by no means the only barrier to access to life-saving medicines, but they can play a significant, or even determinant, role in that they grant the patent holder a monopoly on a drug for a number of years. The patent holder's freedom to set prices has resulted in drugs being unaffordable to the majority of people.

On the other hand, a functioning patent system is also supposed to guarantee that the public at large benefits from any innovation, including medicines. Countries have deployed various strategies to strike a balance between private and public interests in their intellectual property systems, and they have had various degrees of success. Getting the balance just right is particularly important for governments

The TRIPS Agreement

The TRIPS Agreement sets out the minimum standards for patent protection all WTO Members must abide by. Unlike in the days before the TRIPS Agreement, countries that are Members of the WTO can no longer rule out granting patents in particular fields of technology, such as the pharmaceutical sector. But the TRIPS Agreement also requires that patents are granted for inventions which, among other things, are new and inventive. There is no internationally accepted definition of either of these terms and different WTO Members have taken very different approaches, deciding on definitions that best suit their needs. For those WTO Members that do now provide patent protection for pharmaceutical products, much of the debate surrounding patents and access to essential medicines has so far focused on safeguards in the TRIPS Agreement, such as parallel importation, compulsory licensing and government use, that take effect after a patent has been granted. However, even when fully implemented, the TRIPS Agreement still allows some degree of decision making by WTO Members before a patent has been granted, i.e. about what sort of inventions they will grant patents for.

“Patents have been one of the most hotly debated topics on access to essential medicines since the creation of the World Trade Organization (WTO) and the conclusion of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1994.”

of developing countries as they work to protect public health while making their patent laws TRIPS compliant.

A full and frank re-appraisal of the role that a patent system plays in public health alongside other public policy tools is now taking place. The WTO 2001 Doha Declaration on TRIPS and Public Health has played a powerful role in this process. Another important development has been the publication of the report of the UK Commission on Intellectual Property Rights" Integrating Intellectual Property Rights and Development Policy" in September 2002, which strongly advocated for patent systems that support the public health policies of developing countries, according to the needs and level of development of each country.

This paper is written with an aim to introduce some basic features of pharmaceutical patents and evaluate the criticism offered by multinational pharmaceutical companies on Patent Ordinance 2000 as amended under Patent (Amendment) Ordinance 2002. The paper is divided into two parts. Part I deals with conceptual issues relating to pharmaceutical patents whereas part II deals with some of the critical provisions of Patent Ordinance.

Part I

1.1 KEY CONCEPTS IN DRUG PATENTS

Patent systems have a long history. They developed as a way to promote innovation, originally either by encouraging the importation of new technologies into a country or by making new inventions. Instead of keeping the invention a secret, countries learned that one effective way of getting inventors to publicly disclose their invention was to offer them limited monopoly rights in exchange for doing so. One way these patent rights were limited was in time, e.g. 7, 14 or 20 years. After this period of time the monopoly rights were lifted and everybody could use the invention freely.

If the invention was not a success, the applicant would abandon the patent application, or stop paying the annual fees to the patent office to keep the patent alive. So, in theory, the public learned quickly about a new invention when the patent application describing the invention was published, and eventually got free access to use it. In the meantime, the patent holder profited from the patent by selling the new invention at a higher price than would have been the case without a patent since the patent monopoly prevents competition. In an ideal case, both parties benefit from this patent bargain. Adopting a patent system is supposed to encourage investment of resources in making inventions. Research and development (R&D) for new medicines, and in particular the progress in modern Western medicine, is often given as a good example. In fact, R&D into medicines for some diseases is a good example of exactly the opposite. For neglected diseases which only affect poor people, a patent holder will never be able to make a profit by charging high prices, so little R&D is conducted on these diseases. The argument for a patent system encouraging R&D for medical needs in their countries falls far short.

Whether or not the patent system delivers the right R&D, the patent monopoly means that a higher price than necessary has to be paid for patented inventions. This is acceptable if this higher price is merely an inconvenience (say, if you can't afford a new patented pen, you can always still use a cheap, old-fashioned pen, or a pencil). However, if the patented invention is essential (say, if it could prevent your untimely death from a disease), then the price is more of a dilemma. To give a concrete example, the price patent holders charge for an AIDS drug cocktail remains at around US$10,000 in

“Instead of keeping the invention a secret, countries learned that one effective way of getting inventors to publicly disclose their invention was to offer them limited monopoly rights in exchange for doing so.”

rich markets. But because generics companies are able to make their own version where there are no patents to prevent them, these drugs are now available to patients in some developing countries for less than US$300.

Accordingly, it is crucial that a careful decision is made to distinguish between what should be allowed to be patented and what should not. Before the WTO TRIPS Agreement was signed, states were free to determine what would or would not be patentable within the country. States didn't make one-off, long-term decisions on patents. What they allowed to be patented varied a lot over time depending on the state of development of the country. The scope of patents has not always been expanded; in fact, states have sometimes decided to deny the patentability of inventions that were previously patented, or even abandoned their patent system altogether. The patenting of essential goods such as medicines and foods was for a long time thought to be against the public interest. Indeed, when the Uruguay Round of WTO trade negotiations was launched in 1986, more than 50 countries were not granting patents on pharmaceuticals.

Patents rights are territorial in nature like all other intellectual property rights. It is equally true in case of pharmaceutical patents. The general theme to bear in mind is diversity: different countries have the flexibility to adopt different options in designing their patent systems to best suit their own needs. What works for an OECD country may not work for us. A patent may be granted for an invention in one country, yet it may be perfectly legally rejected in another. A patent that has been granted in a country may be revoked if it turns out the patent office should not have granted it.

1.2 Coverage of Drug Patents: One Drug, Many Patents

Many people assume that a patented medicine is protected by one particular patent. Unfortunately, it is not as straight-forward as that. Patents do not protect medicines as such, but "inventions". In the pharmaceutical sector, such an invention may for example relate to a product (e.g. a specific molecule), a process (e.g. the process to manufacture this molecule), a medical indication (e.g. the effect of this molecule on a human body), or a combination of products (e.g. a fixed dose combination of two molecules). As a consequence, a single medicine can be protected by a large number of separate patents, each relating to a different invention.

A company doing basic research for the treatment of a particular disease may discover (or rather, invent) a promising

“Many people assume that a patented medicine is protected by one particular patent. Unfortunately, it is not as straight-forward as that. Patents do not protect medicines as such, but "inventions".”

new chemical entity, or molecule, and so a patent application could be filed for this "new" chemical entity (as well as a way of making it). If, as is often the case, the new molecule was actually a whole family of related molecules, it may subsequently be found that a specific sub-group or element of that family is more promising (a so-called selection invention). It may also be that a particularly effective form (e.g. a crystalline form or an optical isomer) is found, or that it is discovered that this new molecule works particularly effectively in combination with another known molecule. Forms of the active ingredient that appear after a substance has been taken and the body has metabolized it may additionally be found. All these related yet separate inventions may be translated into separate patent applications. Once the best active ingredient(s) have been identified, it may be that the focus of the effort shifts to ways in which they can be delivered, i.e. in what form they should be manufactured. Patent applications on formulations (including. powders, tablets and capsules) may then also be filed. New methods of production may be found. Even years later, scientists may discover that the molecule works against another disease or affliction than the one(s) it was originally patented for, and another patent application (or set of patent applications) can be filed for this "new use" of the now old molecule.

In keeping with the patent bargain, the subject matter of each patent must become available for public use at the end of the patent term, which according to TRIPS Article 33 is now 20 years from the filing date of the patent application. If a later patent application tries to re-monopolize the invention as described in an earlier patent, it should be rejected. Clearly there is a significant threat that patent holders will, in effect, be able to extend their 20-year monopoly on the basic molecule by obtaining a series of new patents derived from the basic patent, each new patent based on inventions of the sort listed above and each with their own further 20-year period of monopoly. This process is known as "ever-greening" and is by no means a secret in the pharmaceutical industry.

1.3 Subject Matter of a Patent must be New

The first fundamental requirement for a valid patent is that the invention is novel. The TRIPS Agreement does not dictate any particular approach to novelty. It is therefore for each WTO Member to determine what is new and what is old. A typical example of a definition of novelty can be seen in Patent Ordinance 2000. It provides that "an invention shall be considered to be new

"The first fundamental requirement for a valid patent is that the invention is novel. The TRIPS Agreement does not dictate any particular approach to novelty."

if it does not form part of the state of the art". The "state of the art" is defined to comprise "everything made available to the public by means of written or oral description, by use, or in any other way, before the date of the filing of the patent application". Although this may sound complicated, it is really just the common sense idea that nobody should be allowed to get a patent for something that the public already knew about. A written description is the most commonly encountered form of disclosure and can include papers published in journals, articles in magazines and patent applications that have been published. An example of oral disclosure might be a researcher describing the invention in a presentation to a conference. Other categories of disclosure include using or demonstrating the product in public, or selling the product.

Priority rights are an important concept relating to novelty. In the late 19th century the country-by-country novelty requirement made it difficult for inventors to have their invention protected by patents in several countries. If the invention was made public after a patent application had been filed in one country but not yet in a second country, then when the patent application was eventually filed in the second country, the invention would already be known there and so it could no longer be considered new. Problems like this made it impossible for inventors to obtain patent protection in as many countries as they wanted to. What was needed was a way for each similar patent application filed in a different country to be treated in the same way, as if it was being filed for the first time. This is exactly what the Paris Convention for the Protection of Industrial Property, originally signed in 1883, solved by inventing the "right of priority". Under the Paris Convention, the first regular filing of a patent application in a country gives a right of priority to the applicant for the filing of similar patent applications in the vast majority of other countries for a period of 12 months. The novelty of the invention is thus artificially maintained during those 12 months. The practical consequences of this are important: it is the priority date that a patent office looks at when examining novelty, although the patent term will start running from the filing date.

1.4 The Subject Matter of a Patent must be Inventive

It is not enough for a patentable invention just to be new. In exchange for 20 years of monopoly rights, the inventor should have to give something very valuable to the public. Accordingly, the second fundamental requirement for a valid patent is that the invention involves an inventive step. But working out a technical definition of inventive step is much harder than defining novelty. Whether or not an invention is novel can be determined on the basis of rela-

“The second fundamental requirement for a valid patent is that the invention involves an inventive step.”

tively clear-cut tests; whether or not an invention is obvious is much more a matter of opinion. According to Patent Ordinance 2000 "an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art". Who or what is a person skilled in the art, though? According to common practice, this person is to be viewed as an ordinary researcher in the field. (S)he will be regarded as having all the "standard" knowledge available in the field and having the "standard" capabilities for "routine work and experimentation" allowing straightforward progress from what is already known. The key thing that a patent application should therefore demonstrate is a step forward which such a person could not have thought of.

A good indicator to demonstrate an inventive invention is whether it produces some surprising or unexpected effect. Imagine two drugs, one that makes people 5cm taller and one that makes them 5cm thinner. If a patient took the two together and got 5cm taller and 5cm thinner, that is just what you might have expected and the combination of the two cannot be said to be an invention. But if a patient took the two together and became completely resistant to malaria instead, this would be a surprising "synergistic" effect and the combination of the two could be a new and separate invention. How surprising (or non-obvious) the invention has to be before a patent is granted in each country should depend on the practice of each patent office, following the rules decided in each country, which can of course vary over time as well. An invention may be regarded as being obvious in some countries, but it may be regarded as surprising in others. So, setting the level of inventive step required is another important choice open to every WTO member. The current low standard of inventiveness applied in developed countries has resulted in a "proliferation" of patents for trivial inventions which may not contribute to the over-riding objective of the patent system which is the advancement of science for public benefit. Patent Office in Pakistan has never refused a patent application which clearly spells out the lack of capability of the Patent Office to apply standards of inventive step suitable to Pakistani situation.

1.5 Patentability of New Use Inventions

Deciding whether an invention is new or inventive and whether it should be patented requires answering some difficult questions. Of particular importance to the patenting of pharmaceutical inventions are new use inventions. Imagine that a particular product is already known for a particular purpose (e.g. AZT as a cancer drug since the 1960's). Imagine then that a new use is found for this product (e.g. AZT

“Deciding whether an invention is new or inventive and whether it should be patented requires answering some difficult questions.”

How inventive are "combination" and "formulation" inventions?

Combination therapies are a vital tool in the fight against HIV/AIDS and many other diseases. It is well known that if a single medicine is used against an infectious agent, the agent may become resistant to that medicine. One way of reducing this likelihood is to use more than one drug at once since it is less probable that the agent will develop resistance to both attacks simultaneously. Antiretroviral (ARV) treatment is a good example of this, triple therapy now being the recommended approach. The best possible way to deliver these combination therapies is in a single pill to increase compliance and reduce resistance.

A leading example of a fixed dose combination (FDC) medicine combining two known ARVs is Combivir, the trade name given by GlaxoSmithKline (GSK) to their combination of zidovudine (AZT) and lamivudine (3TC). An example of an FDC combining three known ARVs is Trizivir, the trade name given by GSK to their combination of AZT, 3TC and abacavir. In this case, GSK also happens to own the patents for the compounds AZT, 3TC and abacavir. If one looks at the patent profile of GSK, it would be realized that GSK has obtained patents widely for both Combivir and Trizivir and has filed for or obtained patents for a particular formulation of these drugs. In order to be able to obtain valid patents to protect each of these inventions, GSK should have demonstrated (or should be able to demonstrate) that the combinations and formulations involved are not obvious.

GSK first filed a patent application back in 1991 to protect the broad "idea" of using AZT and 3TC in combination. The patent application states that using the two drugs together has a surprising effect in that e.g. the emergence of resistance is reduced. Patents were granted quickly in OAPI and South Africa. Later on a patent was granted by EPO but was quickly opposed by Novartis. This opposition was partially successful and the scope of the GSK patent was reduced.

GSK then filed another patent application in 1995 to protect the broad idea of using AZT, 3TC and abacavir in combination. The patent application says that using the three drugs together has a surprising effect in that e.g. the emergence of resistance is reduced. Such patents have been granted in e.g. EPO and ARIPO. GSK then filed a patent application in 1996 to protect the combination of AZT and 3TC in a tablet formulation (AZT, 3TC and a non-active ingredient, a glidant). A patent for this invention has been granted by OAPI, ARIPO and South Africa but is still under examination by EPO.

It is important to follow up what happens in EPO and compare that with the patents already granted elsewhere. GSK then filed a patent application in 1998 to protect the combination of AZT, 3TC and abacavir in a tablet formulation (this time AZT, 3TC, abacavir and a glidant.

as an antiretroviral drug in the 1980's). Should a patent be granted for this new use? One way of looking at this might be to say that it is the same old product, but that we now know more about it, and someone has discovered (rather than invented) a new therapeutic use of it. Another way of looking at it might be to say that, in terms of its new function in life, the product is brand new, so

it should be seen as novel.

The TRIPS Agreement gives no guidance in the matter as it only requires WTO Members to grant patents for products and processes, thereby leaving Members free to determine their own approach. Most experts agree that "even though the TRIPS text does not specify any exception to new uses for known substances, it can be concluded that TRIPS does not require the grant of such patents". There is no accepted international doctrine on the matter. Some countries have decided to grant patents for new uses as product patents, others as process patents, or as a separate patent category. Others have decided to deny the patentability of such new uses for lack of novelty, inventiveness or industrial applicability, or because such a use may amount to a method of medical treatment (which may be excluded from patentability under TRIPS), or because new uses are just discoveries related to a known product and therefore not real inventions.

This aspect of patentability is an important issue of public policy for developing countries like Pakistan. We shall deal with Pakistani position on this issue in Part II of this paper. Here it would be pertinent to highlight experiences of some developing countries. At the time of the TRIPS negotiations, the patent laws of several developed and developing countries excluded from patentability any new uses for known substances. The search for newer and more effective treatment of diseases has to [be] balanced against the well known exclusion of medical methods of treatment and substances already in the public domain. The implementation of TRIPS in the patent laws of developing countries such as the Andean Group expressly excludes second use of known substances. Others like Brazil and Argentina do not have specific exclusions or inclusions to cover this. This means that they could exclude such "second use" inventions as not being novel or inventive enough to qualify for a patent grant. Korea, on the other hand, explicitly deleted the exclusion of new uses of known chemical substances with effect from 1 July 1987 under its bilateral understanding with the US following action under Section 301.

Countries of the Andean Community as well as Kenya resisted pressure from multinational companies and industrialized countries and expressly excluded new uses from patentability in order to limit the number of patents granted in the pharmaceutical sector. The UK CIPR report recommended that "most developing countries, particularly those without research capabilities, should strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products".

1.6 Revocation of Patent

Not very surprisingly a granted patent may be partly or

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“Developing countries like Pakistan have the same sovereign right as developed countries to interpret international agreements with regard to their own needs, when these provisions are unclear or not uniformly accepted.”

The right to reject patents for second medical use inventions: The Andean example

According to Article 21 of Decision 486, Common Intellectual Property Regime, of the Andean Community, "products or processes already patented and included in the state of the art…shall not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent".

Despite this exclusion in the common legislation, an unexpected legislative decree was passed in 1997 in Peru, clarifying that patents may be granted for new uses if it complies with the requirements of novelty, inventiveness and industrial applicability. This resulted in the patent office of Peru granting a second medical use patent to Pfizer in 1999 to protect the anti-impotence drug “Viagra”. The generic industry association of Peru complained about this patent to the Secretariat of the Andean Community, which brought the dispute to the Andean Tribunal of Justice. Although powerful forces were involved (14 lawyers to defend Pfizer and the Government of Peru against two for the Secretariat of the Andean Community), the Tribunal ruled that the Government of Peru had violated the regional patent legislation in granting such a patent.

Developing countries like Pakistan have the same sovereign right as developed countries to interpret international agreements with regard to their own needs, when these provisions are unclear or not uniformly accepted. It remains to be seen whether similar efforts can be mounted for less lucrative but more essential drugs.

completely invalid. A patent may be invalid for various reasons. On closer inspection, it may fail one or more of the tests that it was supposed to pass when it was granted. Patent Ordinance 2000 lays down the grounds for revocation on the basis that the invention is not patentable (for example, the invention falls into a category which is excluded from patentability, such as therapeutic or surgical methods, or the invention is not new or is not inventive), that the patent is not clear enough about how to carry out the invention, that the patent application or the granted patent has been amended in a way which is not permissible, and

that the patent was granted to somebody who was not entitled to it. Some concrete examples include:

- A mistake may have been made during the granting process about whether or not the invention should have been patentable. For instance, GSK claimed to have various patents protecting its antiretroviral medicine Combivir in Ghana, in order to stop a drug distributor from importing a generic version of this medicine in 2000. Investigations revealed that in fact three of the four GSK patents should not have been granted in the first place, as pharmaceutical inventions were not patentable under the previous Patent Law of Ghana.

- Even if the invention falls into a patentable category the patent office may have made a mistake in judging novelty or inventive step in light of the state of the art that the patent search revealed.

- Documents (or something else) describing the invention dating before the priority date may turn up, in which case the invention might no longer be novel or inventive. These sorts of things happen frequently in industrialized countries.

- As was mentioned earlier, TRIPS Article 29.1 obliges WTO Members to require that patent applications "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art". The fact that such a person, for example working in a generic manufacturing company, can prove that it is not possible to carry out the invention on the basis of the information provided in the patent document could also be a motive for revoking the patent.

“Even if the invention falls into a patentable category the patent office may have made a mistake in judging novelty or inventive step in light of the state of the art that the patent search revealed.”

Part II

> “Civil society groups and local pharmaceutical industry harshly criticized the Ordinance and the TRIPS-plus approach adopted in the law. In 2002, Government of Pakistan formally agreed to re-open the law to address the public health concerns raised by the civil society and local pharmaceutical industry.”

Patent (Amendment) Ordinance 2002

In an attempt to comply with the obligation of WTO-TRIPS Agreement; Government of Pakistan has promulgated a new patent law in 2000. The legislation contained various TRIPS-plus provisions by overshooting minimum requirements of the TRIPS. Civil society groups and local pharmaceutical industry harshly criticized the Ordinance and the TRIPS-plus approach adopted in the law. In 2002, Government of Pakistan formally agreed to re-open the law to address the public health concerns raised by the civil society and local pharmaceutical industry. This process concluded in December 2002 resulting in few very important amendments in Patent Ordinance i.e. Patents (Amendments) Ordinance 2002. Obviously these amendments were not welcomed by the multinational pharmaceutical industry and a clear reflection of the effect can be seen from 301 Report of United States Trade Representative (USTR) 2003 and International Intellectual Property Alliance (IIPA) 2003 recommendations to USTRA. This part of the paper will elaborate some of the important changes made in the Ordinance and try to evaluate the compliance of these amendments with the obligations of TRIPS Agreement. The analysis is made while taking the view point of all stakeholders into consideration.

2.1 Definition of Invention

Section 2(i) of the Patent (Amendment) Ordinance 2002 reads as following:

"invention" means any new and useful product or process, in any field of technology and includes any new and useful improvement of either of them."

Whereas the original section 2(i) of the Patent Ordinance 2000 was as following:

"invention" includes any new and useful product including chemical products art, process method or manner of manufacture machine apparatus or other article; substance or article or product produced by manufacture and includes any new and useful improvement of any of them and an alleged invention."

Analysis

This amendment is aimed at reducing the possibility of "evergreening" patents which are quite rampant in pharmaceutical industry. The objective and non-specific

language employed in 2002 amendment and the deletion of "…and includes any new and useful improvement of any of them and an alleged invention" from Patent Ordinance 2000 show that the patent policy in Pakistan would not allow the grant of pharmaceutical patents which are not related to new chemical entities, that is, active ingredient that represent a fresh contribution to the stock of products available for medicinal use. There are different connotations regarding "things and their uses" in patent legislations of different jurisdictions. It can broadly be categorized as following:

- New thing with an advantage
- New use of an old thing
- Selection patents
- New advantage of an old thing

A "use" claim may be either a product claim or a process claim, depending on the context. In Europe, first medical indications have been dealt with as a product claim, whereas the second medical indications as a process claim. Nothing in the TRIPS Agreement obliges Pakistan to introduce additional protection for the first and second indication. While the TRIPS Agreement obliges Member States to protect products and processes (Articles 27.1 and 28), it does not specifically refer to the protection of new uses, thus leaving Member countries free to choose whether or not to protect them. So the Patent (Amendment) Ordinance 2002 is a step in right direction and in original Section 2 (i) was a TRIPS -plus provision with a likelihood of many adverse public health implications.

2.2 Patentability of Substances Existing in Nature

According to Section Section 7 (2) (e)the following shall not be regarded as invention within the meaning of sub-section (1), namely:

"(e) substances that exist in nature or if isolated there from."

Analysis

Some critics consider that this provision is problematic in its existing form. To them there would be no problem to provide this exception to the extend of "substances that exist in nature" but the expression "if isolated therefrom" is not compatible with internationally acceptable patent norms and in fact, to them, it is technically unsound to incorporate such provisions in law because it may hinder the patentability of micro-organisms which exist in nature in isolated form.

The specific language of TRIPS Article 27.3(b) allows countries to exclude from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." The intention of this provision was

“Nothing in the TRIPS Agreement obliges Pakistan to introduce additional protection for the first and second indication.”

“ Unity of invention or restriction assures that the burden for examination is not too great (by requiring searching of multiple fields of art for different inventions included in the same application) given the single payment for examination of claims within a single application. ”

clear that at least micro-organisms must be covered by patents. However, it is less clear that other types of isolated substances must be included. The background to the exception was an effort to assure coverage for isolated and purified chemicals (particularly pharmaceuticals) and for isolated and purified biological materials and organisms (including chimeric organisms).

The status of isolated and purified materials (gene sequences and proteins) under TRIPS is subject to debate, particularly because it may conflict with the Convention on Biodiversity (CBD) and moral concerns. By virtue of Section 7 (4) (b) micro-organisms are obviously patentable as per requirement of TRIPS Article 27.3 (b), but isolated and purified substances other than microorganisms could be argued to be within the exclusion of 27.3(b). This is, however, a highly controversial issue and if Pakistan were to exclude biotechnology from patentable subject matter Pakistan might encounter trade pressures to reverse the decision from countries where biotechnology is an important industry. In the light of above discussion we can conclude that the amendment is sound and there is no violation of TRIPS obligation if all the provisions of patent ordinance are put together.

2.3 The Issue of Unity of Invention

According to Section 13 (3) of Patent. (Amendment) Ordinance 2002:

"Each application shall relate to one invention only".

Whereas the original section 13 (3) of Patent Ordinance 2000 was as following:

"Each application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept".

Analysis

Many patent systems require "identity of invention" or "unity of invention" and will not allow examination of unrelated inventions or may require "restriction" to a single invention. In the U.S., restriction is at the discretion of the Patent Office. Unity of invention or restriction assures that the burden for examination is not too great (by requiring searching of multiple fields of art for different inventions included in the same application) given the single payment for examination of claims within a single application.

Thus, the Patent Cooperation Treaty (PCT), Article 17(3) provides: "(3)(a) If the International Searching Authority considers that the international application does not comply with the requirement of unity of invention as set forth in the Regulations, it shall invite the applicant to pay additional fees. The International Searching Authority shall establish the international search

report on those parts of the international application which relate to the invention first mentioned in the claims ("main invention") and, provided the required additional fees have been paid within the prescribed time limit, on those parts of the international application which relate to inventions in respect of which the said fees were paid." Similarly, the Paris Convention, Article 4(G) (1) provides that "If the examination reveals that an application for a patent contains more than one invention, the applicant may divide the application into a certain number of divisional applications and preserve as the date of each the date of the initial application and the benefit of the right of priority, if any."

It is believed that this provision would be fully consistent with existing international norms, although a permissive option to include more than a single invention and for the patent office to require additional payment to examine additional inventions in the same application may be preferable.

2.4 Patents Related to Genetically Modified Organisms

Section 13 (8) of the Patent (Amendment) Ordinance 2002 states:

"An application for an invention relating to genetically modified organisms shall require clearance from the Federal Government and shall comply with such requirement as may be prescribed".

Analysis

The Government of Pakistan has yet to introduce a comprehensive regulatory framework governing the inflow of genetically manufactured/modified/manipulated products in Pakistani market. It is assumed that the proposed Bio-safety guidelines will address this issue and a cautious approach would be adopted in this regard. Section 13(8) has been incorporated to address this policy objective that GM products should be regulate and before filing patent application a clearance certificate should be sought from the Federal Government to ensure that the product has no adverse environmental and ethical consequences.

The provision has a value addition especially in the absence of any regulatory framework dealing with the introduction of highly controversial GM products in Pakistan.

2.5 Specification of Pharmaceutical & Chemical Product

According to Section 15 (2A) (read with Section 15(8)) of Patent (Amendment) Ordinance 2002:

"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,

“The Government of Pakistan has yet to introduce a comprehensive regulatory framework governing the inflow of genetically manufactured/ modified/ manipulated products in Pakistani market.”

“ Although the TRIPS agreement identifies in Article 29 the required disclosure elements, it does not prohibit national laws from adopting more restrictive standards on permissible claims. ”

pharmacological and pharmaceutical properties or, as the case may be the properties related to its use in agriculture and its impact on environment".

Section 15 (8) states:

"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 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".

Analysis

This is another tricky issue. Section 15(2A) appears to relate to the unity of invention point discussed above, although it may adopt an unusually restrictive definition of a single invention specific to such chemical products. Section 15(8) appears to combine three separate elements. The first is a unity of invention requirement, restricting from the definition of invention salts and other derivatives. The second is a claim form requirement, that the claim be drafted in structural terms unless it is not possible, and then in product-by-process terms. The third is a prohibition against claiming inventions that are unreacted, non-synergistic chemical mixtures that exhibit aggregated properties of the components (or processes for producing such mixtures).

The unity of invention component is even more restrictive than 15(2A), and is not customary. However, there are significant issues regarding the ability to claim all derivatives of known structures. The normal concepts for evaluating whether such claims are permissible include adequacy of the written description (and whether the inventor has actually invented all of the derivatives that might be claimed), adequacy of enablement of the full scope of a claim that includes all derivatives, and definiteness of a claim that is drawn to that scope. Although the TRIPS agreement identifies in Article 29 the required disclosure elements, it does not prohibit national laws from adopting more restrictive standards on permissible claims. Thus, even if it was not a unity of invention issue, a flat prohibition on claims drawn broadly to include salts and mixtures would likely be permissible. For this reason, the requirement that the claim be drafted in structural terms (and limited to the particular forms

without derivatives) also should be permissible. However, the prohibition against claiming mixtures may be more suspect.

The question is whether such a mixture should be considered not an invention in the first instance or an "obvious" invention, i.e., without sufficient inventive step. TRIPS does not define "invention," and did not establish uniform standards for determining obviousness of inventions. However, an argument might be made that this provision discriminates in defining excluded inventions by field of technology (TRIPS Article 27.1). The provision might therefore be better drafted by explaining the standard of obviousness and why such mixtures may be obvious and un-patentable.

PCT Article 33(3) provides "(3) for the purposes of the international preliminary examination, a claimed invention shall be considered to involve an inventive step if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art." In turn, the PCT Rule 33.1(a) defines prior art for determining inventive step or obviousness, and Rule 65.1 specifies the approach to be taken (considering the invention as a whole) when determining inventive step or obviousness. However, the PCT does not restrict national legislation to define what inventions should be considered obvious. PCT Article 27(5) provides that "(5) Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires." Similarly, the TRIPS Agreement and the Paris Convention do not establish restrictive standards for national legislation to determine obviousness.

Article 27.1 of the TRIPS Agreement requires that patents be available, subject to the criteria of novelty, industrial applicability, and inventive step, without discrimination by field of technology. These requirements would clearly create different standards of patentability for specific chemical inventions. However, the prohibition on "discrimination" should be understood not as prohibiting any type of differential standards but rather as prohibiting unjustified differential standards, which is suggested in the Dispute Settlement Decision in the Canada-Pharmaceuticals Case in the WTO. In addition, except for the mixture issue, these provisions do not in any way make patents "unavailable" for the applicable chemical inventions, but rather require that that they be processed in separate applications.

In sum, these provisions should be consistent with international law obligations.

2.6 Use of Biological Material in Patented Inventions

Section 15 (2B) of the Patent (Amendment) Ordinance 2002 states:

“The question is whether such a mixture should be considered not an invention in the first instance or an "obvious" invention, i.e., without sufficient inventive step.”

"Where a biological material is used, the specification shall disclose the place of origin and source of such biological material and shall also exhibit compliance with the relevant applicable rules on access, export and use of that material any where such a material is obtained from Pakistan".

Analysis

This section has been incorporated to address the concerns of bio-piracy in developing countries like Pakistan. The TRIPS Agreement provides a wide discretion to the member countries to articulate their needs and demands of patent applications specification in national laws. Given the fact that at the moment no other law effectively deals with the problems arising out of bio-piracy, it would be useful to strictly follow the approach enumerated in Section 15 (2B).

2.7 Mail Box Provision, Exclusive Marketing Rights & Local Manufacturers

According to Section 30 (4A) of the amended Ordinance:

"Where a person has made an invention in Pakistan in respect of a process of manufacture of any of the products referred to in subsection (4) and has obtained a patent for the same and has filed an application in the mail-box 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."

Analysis

This new section is an attempt to put local manufacturer at par with their foreigner competitors to face the problems arising out of mail-box and exclusive marketing rights provisions. There is no doubt that section 30 (4A) is quite unique and original in its nature and its boarder application and interpretation can nullify the benefits granted to potential patent holders under Article 70.8 & 70.9 of the TRIPS Agreement. It should also be kept in mind that this section would no longer be applicable after 2004 once product patent will become reality. Given the fact that no internationally accepted norms are existing which govern the operations and scope of mail-box & EMR provisions and the limited practical significance of amendment, it is recommended that any review of this provision should be dropped from the agenda.

2.8 Doctrine of Exhaustion & Parallel Importation

Section 30 (5) (a) of amended Ordinance states:

"The rights under the patent shall not extend to-(a) acts in respect of articles which have been put on the market anywhere to the, world

“Given the fact that no internationally accepted norms are existing which govern the operations and scope of mail-box & EMR provisions and the limited practical significance of amendment, it is recommended that any review of this provision should be dropped from the agenda.”

by the owner of the patent or with his consent or by an authorized person or in any other legitimate manner such as compulsory licenses".

Whereas Section 30 (5) (a) of the Patent Ordinance 2000 was as following:

"The rights under the patent shall not extend to-(a) acts in respect of articles which have been put on the market by the owner of the patent or with his consent."

Analysis

This section deals with the doctrine of exhaustion and parallel importation. The amendment broadens the scope of parallel importation by adding some new situations of exhaustion. TRIPS Agreement deliberately refrains from dealing with the highly volatile issue of exhaustion of patent rights and leaves this matter to be decided by member countries according to their domestic policies.

It is argued by multinational Pharma that a liberal parallel importation regime would not be in the best interest of Pakistani consumers because it would ultimately lead towards elimination of differential pricing and would also entail many issues of quality and efficacy. One can very easily rebut this presumption by highlighting the very fact that in a regulatory atmosphere of price regulation like Pakistan, the phenomenon of differential pricing is not merely a matter of choice! The issue of quality and spurious drugs is also a general phenomenon and cannot be essentially linked with parallel importation. Moreover parallel importation has been recommended by the WHO as an important drive to ensure people's access to medicines. The amended provision should remain part of the law and it is quite an important provision from public health point of view.

2.9 Data Exclusivity

Patent Ordinance 2000 as amended in 2002 is silent on the issue of protection data submitted to the ministry of health for registration purpose. Multinational Pharmaceutical companies consider it to be a negative aspect of patent legislation and consistently lobbying that this issue should be addressed under patent law.

The development and bringing to market of a new drug requires the originator to conduct extensive chemical, pharmacological, toxicological and clinical research and testing. The data generate d by such work, while proprietary to the originator, must be submitted to the regulatory authorities of countries around the world in order to obtain approval to market the drug. Such data should be protected against the unauthorized use as per requirement of Article 39.3 of TRIPS Agreement. Multinational Pharma alleges that at the moment their data submitted to Ministry of health is misused and patent ordinance fails to address

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this issue. In fact pharmaceuticals and agricultural chemicals (pesticides) are required to be registered with the Ministry of Health prior to their sale within the country. The protection of undisclosed data or information submitted to obtain registration is provided through a number of laws:

- Section 18 of the Civil Servants (Conduct) Rules, 1964 requires that no government servant shall communicate directly or indirectly any official document or information to a government servant unauthorized to receive it, or to a non-official person, or to the press.

- Wilful communication of information (which a government servant has obtained or has access to by virtue of his holding an office) to a person unauthorized to receive it, is an offence under Section 5 of the Official Secrets Act 1923. Such an offence is punishable with imprisonment which may extend up to two years or with fine or both.

- Rules 55 of the Rules of Business, 1973 also prohibit the communication of information obtained directly or indirectly form official documents or relating to official matter to non-officials, the press or government servants not authorized to receive it.

Any subsequent applicant would, therefore, not be given access to data or information submitted by an earlier applicant. The law does not specify the term of protection.

In the context of pharmaceuticals, Rule 13 of the Drug Rules 1940 stipulates that no person on the staff of the official Laboratory shall disclose to any other person not on the staff any information relating to the composition of a particular patent or proprietary medicine acquired in the course of his duties in the Laboratory. Provided that the Director or any other officer authorized by him in this behalf may with the previous sanction of the Federal Government, disclose any information so acquired to the extent necessary for the purposes of a prosecution under the Drugs Act.

Under Rule 10 of the Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rules, 1976, except for the purpose of official business or when required by a Court of Law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any information acquired by him in the course of his official duties.

In addition, under Section 6 of the Patents Ordinance an, employee of the Patent Office is forbidden to divulge any information available to him by virtue of his office in respect of any application for a patent or a patent granted in Pakistan, except when required or authorized by this Ordinance or the Controller or by a Court of Law.

About The Network

The Network for Consumer Protection was formed in 1992 with a focus on public health, later expanding its attention to consumer protection. Since then, the organization has become an effective advocacy group, working at the grassroots, national and international levels. The Network activities include public policy advocacy, community mobilization, research and publication.
The Network's programme seeks to assist citizens-consumers to influence public policies in order to meet their livelihood needs and to develop informed opinion on relevant policies. The Network enjoys a track record of compiling and disseminating information for citizens and mobilizing action around key issues.

To join activities of
The Network and receive its publications, consider becoming a member of the organization.
For more details contact:
051-2261085

“Patents have been one of the most hotly debated topics on access to essential medicines since the creation of the World Trade Organization (WTO) and the conclusion of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1994. Patents are by no means the only barrier to access to life-saving medicines, but they can play a significant, or even determinant, role in that they grant the patent holder a monopoly on a drug for a number of years. The patent holder's freedom to set prices has resulted in drugs being unaffordable to the majority of people living in developing countries.”

40-A Ramzan Plaza, G-9 Markaz, Islamabad. Tel: +92-51-2261085. Fax: +92-51-2262495
Email: main@thenetwork.org.pk URL: thenetwork.org.pk