

Patent System and its Legislation in Nepal: An Overview

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Abstract

Patent is one of the major constituents of intellectual property rights. It deals with the protection of technology which has now become a more important factor for both the developed and developing country economies. In the industrialized countries patents are considered as the most valuable economic asset as it has a far-reaching impact on the ability of firms to control the market. However, for the least developing country economies like Nepal the way ahead is still long and difficult for it to be able to take advantage from the patent regime. The main objective of this article is to explore Nepalese patent law and the extent to which it is used by the firms and individuals.

Introduction

Patent is one of the most important branches of intellectual property law dealing with the protection of technology. It is a legal device designed to protect new and useful inventions from their unauthorized use. World Intellectual Property Organization (WIPO) (2001) defines inventions as solution to a specific problem in the field of technology. They are the human creation of a new technical idea and the physical means that can accomplish or embody the idea (McCarthy, 1995). A mere revelation of something which existed and was unknown does not constitute patentable invention. It must be the creation of something which did not exist before (Mansfield, 1968).

As modern economy increasingly came to rely on technological inventions and innovations, patent protection has acquired increasing prominence both in the developed and developing nations. Mark Twain, for example, remarked, "...that a country without a patent office and good patent laws was just a crab, and couldn't travel any way but sideways or backwards" (quoted in Adelman, et al., 1998). Countries that have for a long time relied on patent regime, such as the United States, Japan and European countries may provide a valuable insight on how patent system could be most effectively employed as a powerful stimulus to promote inventions and innovations.

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Patents are important as much to innovations as they are to inventions. Innovations are the first commercial application of new ideas. They require huge investment to develop and bring them into the marketplace which may not be profitable without patent protection. Machlup (1958b), for example, points to the fact that patent incentive may not be needed for inventions to take place but it still is needed "as encouragement for investment and enterprise to introduce untried techniques and products." Innovation is important as invention without its application is useless.

Patent law distinguishes invention between two categories: product and process inventions. Product invention relates to a material object which includes structure, apparatus or a chemical composition. Patents granted for product are called product patent. In contrast, process invention relates to the method or process of making a product and includes an act or a series of acts which operate upon an object producing a certain product or result (Franzosi, 2002). Patents granted for process are called process patent. An invention of a new alloy, for example, would be a product patent whilst the invention consisting of a new method or process of making a known or new alloy is a process patent (Alikhan, 2000).

Patents are aimed at promoting the creation of technical knowledge that leads to the development of new and useful inventions and innovations in every aspect of human life. Inventions and innovations are the key to an overall economic health and well-being of the society. They are critical components to the growth and sustenance of modern, knowledge-based economy and hence the major concern for the industrialized countries. Recent economic growth indicates the predominance of knowledge and technology in every sector of the economy. Firms that are ahead in the development of new technology have greater ability to exercise significant power or control over markets. This perhaps is the reason why patents are regarded as the most valuable economic assets. Around the turn of the twentieth century, Korekiyo Takahashi, the first President of the Japanese Patent Office, visited US Patent Office on his mission to study patent system. There he found a key to economic prosperity and opined as: "We have looked about us to see what nations are the greatest, so that we can be like them. We said, "What is it that makes the United States such a great nation?" and found that it was patents and so we will have patents." (quoted in Heath, 1997). Literature on patent makes frequent reference to this citation to emphasize the role the patent system plays in the industrialization of a country. In a similar vein, Rohrabacher & Crilly (1995) write that America's strong patent laws have served to encourage investment and technological research that has kept this country in the forefront of human progress. They contend that the competitiveness of the United States is tied to its ability to take the lead technologically.

Patent is the grant of exclusive right to the use of technical inventions for a specified duration in return for the disclosure of the invention (Machlup, 1958a; WIPO, 1989). The exclusive right conferred by patent is essentially a negative right. It is essentially the right to secure the enforcement power of the state in excluding the unauthorized persons from making commercial use of the inventions (Machlup, 1958b). It is a right to exclude others from making, using, offering for sale or importing a patented invention without the

authorization of the patentee. It does not confer on its owner any positive right to practice his invention. This means a patent does not grant an inventor the right to make, use, or sell her invention (Moore, et al., 1999). Patent, like other forms of intellectual property rights, may be assigned, licensed or charged by way of mortgage (Bainbridge, 2002).

Unlike copyright protection which automatically comes into existence at the moment the work is created, patent protection requires a filing of patent application by the inventor and compliance to the statutory requirements of patentability. The patent is granted for a term of 20 years from the filing date. This is the term the TRIPS (Trade-Related aspects of Intellectual Property Rights) Agreement stipulates. However, patent requires the payment of the prescribed annual renewable fee to enjoy the protection to its full term. Copyright, by contrast, does not have such requirement. Patent exclusivities are often referred to as 'monopolies' for they forbid not only imitation, regardless of independent creation of the same invention, but also the use of the concept or technical principles embodied in the invention for any applications. Patent has, therefore, greater strength to ward off competitors and create market power than do other forms of intellectual property rights. It is for this reason patents are viewed in the business community as the most valuable asset for the firms to secure competitive edge over their potential competitors.

Patents in essence are economic incentives to create. The exclusive right which patent confers on its owner enables him to charge a price for the use of his invention which serves as an incentive for him to engage in inventive activities. Absence such incentives, it is assumed that many of the important and useful inventions needed for the benefit of the society would not have been created, developed and produced. Mansfield (1986), for example, observed that 65 percent of the innovations generated by the pharmaceutical firms in the United States from 1981 to 1983 would not have been marketed and 60 percent would not have been developed, if patent protection had not been available. Availability of patent protection is critical to the decision about investment in innovation in these sectors where fixed costs of R&D are high and imitation is fairly easy. However, patent protection may not be equally important across different industries. In an empirical study by Mansfield (1986) of 100 manufacturing firms in the United States, patent protection was reported to be of limited importance in electrical equipment, office equipment, motor vehicles, instruments, primary metals, rubber and textiles. Corresponding to Mansfield's finding, Levin (2000), for example, found the effectiveness of patents highly non-uniform across 130 different industries he surveyed. In general, patents were viewed by R&D executives as an effective instrument for protecting the competitive advantages of new technology in most chemical industries, including the drug industry, but patents were judged to be relatively ineffective in most other industries. In a similar vein, Abbott (1998) concludes that the impact of intellectual property rights is case sensitive differing from sector to sector. The role of the patent in the process of development of an automotive sector is quite different from the role of the patent in the development of a pharmaceutical sector.

Justification for Patents

From its very beginning, patent has a fundamentally economic orientation (Adelman, et al., 1998). Arguments in justification of patent protection are premised on natural law, on moral requirements or on economic considerations (Machlup, 1958a). However, more popular among these arguments are those based on economic considerations. According to their emphasis, these arguments may be grouped into three categories: the incentive to invent, the incentive to disclosure and the incentive to innovate.

The incentive to invent argument holds that inventions will suffer in the absence of patent protection because original inventor may not be able to recoup the cost of his invention if it can be quickly imitated by free-riders who do not share any cost in the invention. With low marginal cost of imitation, competition in the market will tend to drive the prices down to a level where it is not possible for the original inventor to realize the fixed costs incurred on the invention. This in turn would retard or discourage the creation of important inventions to the significant loss of social welfare.

The incentive to disclosure argument views patent monopolies as an incentive for the inventor to give up his secret (Machlup, 1958a). Without such incentive, the inventor would prefer to keep his inventions secret to prevent the competitors from using the invention. Secrecy hampers the promotion and dissemination of technical knowledge: it deprives the society from obtaining the benefit of new knowledge and technological information and leads to wasteful duplication of research (Adelman, et al., 1998).

The incentive to innovate argument emphasizes on the need to protect investment to promote innovative undertakings. It is premised on the hypothesis that firms will not undertake large investment needed for complete development and marketing of the inventions if such investments are not protected against competition. Invention by itself does not make much economic sense unless it is developed into a marketable product for commercial exploitation. Use of the invention for commercial exploitation entails large outlays on research and development (R&D) to establish the viability of the invention, on the construction of new plants and equipment, on promotion and advertisement to create mass market, and so on (Machlup, 1958a). These investments being highly risky, the firms would not undertake them unless they are secured by patent monopolies.

Subject Matter of Patent Protection

The subject matter of patent protection covers any new and useful process or product in any area of technology. However, certain technologies may be excluded from the subject matter of patent protection. Most national laws on patent provide exclusion to include: (a) discoveries of materials or substance already existing in nature; (b) scientific theories or mathematical methods; (c) plant or animal varieties or essentially biological processes for the production of such plant or animal varieties, other than microbiological processes; (d) schemes, rules or methods, such as those for doing business, performing purely mental acts or playing games, and (e) methods of treatment for humans or animals as well as diagnostic methods practiced on humans or animals (but not products for use in

such methods). Inventions which are injurious to the well-being, public health or sound morals of society may also be excluded from the protection. This is also clearly provided in Article 27(2) of the TRIPS Agreement which allows its member countries to exclude certain inventions from patentability in order to protect “*ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment”. But such exclusions may not be applied for the purpose other than those stated above. Exclusions not based on the specified grounds provided in the provision will not be considered valid “merely because the exploitation is prohibited by domestic law”.

Ideas *per se* are not protected by patents. What it protects are the ideas that have been embodied in technical applications. This in essence means that ideas are protectible to the extent they have been applied to produce intended result. This precisely is the holding when the U.S. Court in *Mackay Co. v. Radio Corp.* stated: “(w)hile a scientific truth or the mathematical expression of it is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be” (quoted from Adelman, et al., 1998). It is true that patents are more concerned with the protection of ideas than the object which they represent. However, a mere idea that does not suggest ways to carry it out has no relevance for patent protection. This is clearly explained in an English case, *Gale's Application*, where L. J. Buckley said (Cornish, 1996b):

Every invention to support a patent must no doubt be a new manufacture – that is to say, it must either suggest a new way of making something – a means of constructing an old thing in a new manner – or it may mean the way of producing a new article altogether; but I think you are losing grasp of the substance and seizing the shadow when you say that the invention is the manufacture as distinguished from the idea. It is much more true to say that the patent is for the idea as distinguished from the thing manufactured. No doubt you cannot patent an idea, which you have simply conceived, and suggested no way of carrying out, but the invention consists in thinking of or conceiving something and suggesting a way of doing it.

Patentability

To be patentable, an invention must satisfy three basic conditions of patentability: (a) Novelty, (b) Inventive Step, and (c) Industrial Applicability. Novelty is the first and foremost requirement of patentability. Being a legal fiction, novelty cannot be proved or established – only its absence can be proved (WIPO, 1989). The objective of novelty test is to determine whether the claimed invention is different from the prior art. The test involves a 'comparison between the invention, in any of its embodiments, and the thing that is revealed by the prior publication or use'. An invention is new if it differs or is not anticipated by the prior art. It lacks novelty if the technical solution is identical to a solution contained in the prior art. The term 'prior art' refers to all technical knowledge or information that existed or is publicly available prior to the priority or filing date of a patent application by way of written or oral disclosure or by use or in other way. An

invention must satisfy novelty requirement before it merits for further examination to determine its patentability. The novelty test basically serves the function of screening the claims that do not deserve further investigation. Lack of novelty would at once invalidate the patent application without any further inquiry. Novelty, however, does not require the invention to be substantially different from the known invention: a simple difference would suffice to establish novelty.

The second requirement, inventive step is aimed at ensuring that patent be awarded only to those inventions that actually deserve such monopoly grant. If all that novelty requires is a mere difference from the known invention, any such small and frivolous devices as involving a mere application of a known principle or a new use of an old thing or any such insignificant variations may claim for patent protection. Granting patent monopolies to such claims "...would be intolerable nuisances, and would seriously impede all improvements in the practical application of common knowledge" (quoted from Adelman, et al., 1998). The need to exclude the inventions lacking sufficient ingenuity from the scope of patentability led to the inquiry into the obviousness of the alleged invention. This gave rise to new barrier that required the presence of inventive step as an important condition of patentability.

While novelty requires any difference between the claimed invention and the prior art, the inventive step goes a step beyond and requires this difference to be substantial. What then amounts to substantial is measured against the yardstick of a person having ordinary skill in the art. The difference will be deemed substantial as to constitute inventive step if, having regard to the prior art relevant to the patent application claiming the invention, it would not have been obvious at the filing date or the priority date of the application to a person having ordinary skill in the art. The person having ordinary skill in the art is considered to be a person with appropriate technical training and experience. Such a person need not be the best expert in the country in that field. The expression 'ordinary skill' is employed to exclude the 'best' expert that can be found. It is intended that the person be limited to one having the average level of skill reached in the field in the country concerned.

The idea underlying the inventive step is that patent should not be awarded to anything that is trivial, or merely an extension of the knowledge belonging to the prior art. An invention to be patentable must consist of a sufficient degree of originality or ingenuity that constitutes a technical advance over the state of the art. The expression 'inventive step' hence emphasizes on the creative aspect of the invention that should lead to open the new frontiers of scientific knowledge, a step forward from the prior art or that what is already known. It is only for such distinct contribution to the advancement of scientific knowledge that inventors are rewarded with special inducement of a limited private monopoly.

The requirement of industrial applicability demands the invention to be of a kind which can be applied in industry for practical or useful purposes.** Whether it is a product or process, the invention must have a known use for which it can be applied. An invention claiming something that does not work, or is unusable, is not patentable.

The requirement that invention must be capable of being applied to practical use is based on the notion that a grant of patent for the inventions of which the applications are not known or which constitute the basic scientific information, would result in patent for a wide subject matter because the patentee can claim the information in all its uses. This would block or discourage the search by others for product uses which are of practical significance. This often is the case with chemical substance where, for example, the uses of a compound in most instances are not known at the time it is discovered. The subsequent research and investigation is needed to relate the compound to its practical applications. But such research and investigation requiring much effort and investment would not be undertaken if those who worked out and discovered its practical applications were to receive only secondary derivative patents.

The exclusion of discoveries, scientific theories and mathematical methods is based on this logic. These are, however, excluded to the extent that the patent relates to the conception as such. Application of these concepts to practical uses would transform them into a patentable subject matter.

In addition to these three basic conditions mentioned above, the other important requirement for patentability is the disclosure of the invention. The specification which describes the invention constitutes the disclosure of the invention. The specification must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person having ordinary skill in the art. In other words, the specification must teach a person skilled in the art how to make and use the invention. The specification should explain with examples and drawings, wherever necessary and appropriate, at least one mode for performing the claimed invention. A disclosure is deemed to be adequate "when it enables a person of ordinary skill to 'practice' the invention as claimed without undue experimentation or effort" (Lehman, 1995).

In some jurisdictions, particularly in the United States, the specification should describe the 'best' mode of practicing the claimed invention at the time of patent application. This requirement is intended to prohibit the concealment of the best mode of practicing the claimed invention. The best mode requirement is considered as being

** Industry is broadly defined to include agricultural and extractive industries. For example, Article 1(3) of the Paris Convention for the Protection of the Industrial Property provides: "Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco, leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour."

unique to the U.S. patent system. Disclosure requirement with regards to micro-biological process or its products involving the use of a micro-organism envisages a special scheme which demands a deposit of a sample of the micro-organism with a recognized culture collection. Under this scheme, the competitors can obtain the sample of a deposited material for experimental purposes before the applicant knows 'whether or not he will succeed in securing his patent'. As such, this procedure is considered to be highly controversial.

Disclosure is an important aspect of patent system because it provides an invaluable source of technological information. It enables others to understand the technology and be able to use it as a stepping stone to further develop the technology with better inventions and innovations. It is in return for giving up the secrets of their inventions to the benefits of the society that the inventors are rewarded with the limited right to exclude others. The grant of a temporary patent monopoly is in fact a *quid pro quo* for revealing the secret embodiments of the invention.

Scope of Monopoly

Of central importance in the patent instrument are the claims in the specification which are the metes and bounds of the inventor's property right (Moore, et. al, 1999). They define the features of an invention which are protected (Lehman, 1995). The claims delimit the scope of the patent monopoly in that they set the bounds of the technical area within which any activities without patentee's consent would give rise to infringement. This is clearly explained in an English case, *Electrical and Musical Industries v. Lissen* where Lord Russell said (Cornish, 1996b):

The function of the claims is to define clearly and with precision the monopoly claimed, so that others may know the exact boundaries of the area within which they will be trespassers. Their primary object is to limit and not to extend the monopoly. What is not claimed is disclaimed....

The claims must meet four criteria for them to be valid: (1) they must define the protected matter, (2) they must be clear and concise, (3) they must be supported by the description, and (4) they must be related to one invention (unity of invention).^{††} The first three requirements are 'fundamental and used to be open to objection once the patent was granted'.^{‡‡} The requirement that the claims must be related to one invention is aimed at simplifying the classification of specification in an orderly manner which is necessary for the process of searching. By 'unity of invention', as laid down in Article 82 of the European Patent Convention, the patent application must "relate to one invention only or to a group of inventions so linked as to form a single general inventive concept".

^{††} Article 84 of the European Patent Convention (1973) sets forth: "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description."

^{‡‡} Discussion on patent claims draws on Cornish, Intellectual Property.

According to this provision, patent applicants can claim "for a process, the apparatus to operate it and its products or for products, processes for making them and use of the products" (Cornish, 1996a).

The method of claiming system that defines the scope of monopoly according to these criteria is referred to as the 'fence-post' claiming as distinguished from the 'sign-post' claiming where the claims are aimed at broad coverage by specifying the essential embodiments of the invention (Cornish, 1996a). In contrast to the 'fence-post' claiming which marks out the boundary of the area covered by the claim and holds any activities within the area thus defined to be infringement, the 'sign-post' claiming is less direct and definite since it seeks to distinguish what is new from what is old without clearly specifying what it is that is claimed. With the 'sign-post' claiming system, it is difficult to know the exact boundary of the monopoly since the claims are construed to incorporate by reference the description in the specification and equivalents thereof. In most instances, it is only when disputes arise and the court works out the proper scope of the monopoly from the description of the invention that the precise delineation of the claims is established (ibid). The modern claiming system favors the 'fence-post' approach (Cornish, 1996a).

In the United States, the parallel terms for the 'fence-post' and the 'sign-post' claiming are respectively the 'peripheral' and the 'central' claiming system. The courts in the United States have since long rejected "central" claiming system as § 112(2) of the U.S. Patent Code expressly requires that the claims particularly point out and distinctly describe the invention without reading in limitations from the specification (Adelman, et al., 1998). As such, the claims that incorporate by express reference to the specification and/or drawings are deemed invalid except in limited circumstances (ibid). This was clearly stated in an American case, *Ex parte Holt* (quoted from Adelman, et al., 1998):

The aim, end, and purpose of the specification, under the present statute, is to describe the invention sought to be covered by the patent, and the manner of making, constructing, and using the same. The aim, the end, the purpose of the claim is to point out particularly and distinctly define the invention to be secured to the individual. The claim is the measure of the patent, and the day has passed when the courts will search the specification for information which is the very office of the claim to impart.

Of all forms of intellectual property rights, patent protection is much broader to spare any privilege or concession for the competitors to exploit the patented invention for commercial purposes. This is mainly because the exclusive right conferred by patent extends to the right to exclude not "just imitators, but even independent devisers of the same idea...from using the invention for the duration of the patent" (Cornish, 1996a). The market power which the patent exclusivity thus confers on the right owner has relatively greater strength to restrain competition than it does by other forms of protection, such as copyright. Monopoly in relation to patent protection is therefore deemed to be absolute, and it is for this reason patent is viewed in the industrial sector as the most valuable asset of all intellectual property. But to the competitors, patent protection is the most difficult

and formidable barrier to get access to the market, especially in such cases, as noted above, where the patented invention holds tremendous potential to block the creation of non-infringing product without obtaining license from the right owner. This perhaps is the reason why patent protection is not easily granted and is subject to stringent eligibility requirements, such as novelty, non-obviousness and industrial application.

Patent Protection in Nepal

Nepal promulgated laws recognizing copyright and industrial property during the second quarter of the twentieth century. These two laws form a corpus of Nepalese intellectual property code. Law on copyright appeared in the Nepalese code, known as *Muluki Ain*, in somewhat inchoate form in 1935. A year later in 1936 law on industrial property covering patent, design and trademark was enacted. Since their first promulgation, significant changes in these laws have taken place over time. In August 1965, both the copyright law and the patent, design and trademark law were re-enacted. Copyright Act, 1965 was again updated to be replaced by a new copyright act 2002. The law was first amended in 2005 by an ordinance made to amend some Nepal acts relating to export and import and intellectual property. The amendment was specifically intended to comply with WTO/TRIPS stipulations that require its member countries to enshrine the principle of national treatment in their national laws on intellectual property rights. Accordingly, the law extended copyright protection to the works of foreign authors and right holders belonging to WTO member countries.

Unlike copyright law which was completely re-written in 2002 to modernize it no such initiation has been taken in relation to the Patent, Design and Trade Mark Act 1965. The law has been amended thrice (1987, 1991 and 2005) since its enactment in 1965. The third amendment to the act by an ordinance made to amend some Nepal acts relating to export and import and intellectual property appears to have been prompted, as stated earlier, by the need to comply with the minimum requirements of the WTO/TRIPS Agreement.

The Patent, Design and Trade Mark Act, 1965 defines patents as being any useful invention relating to a new method or process of manufacture, operation or transmission of any material or combination of materials or that invented through any new principle or formula (Article 2(1)). This definition, however, is unclear and confusing. The use of the phrase "... operation or transmission of any material or combination of materials ...", assuming this to be an exact translation of Nepali version, is obscure in that one cannot be definite about its intended meaning. Such expression may give rise to several contradicting interpretation obstructing a fair and efficient implementation of the law. By contrast the definition provided under the Patent, Design and Trade Mark Act 1936 is more simple and clear. Article 1 of this Act defines patents as an exclusive right over an object of any new invention (MoLJ, 1995 (2052 B.S.). Invention, in turn, is defined as a new object not known to anyone or not being put into use before the filing date of patent application. In other words, invention that has been anticipated by the previous patent, or publication or use is deemed to have lost its novelty for the purpose of patent acquisition.

By Article 2(1), an invention to be qualified for obtaining patent must be new and useful. But nowhere does the law define what constitutes new and useful with respect to any invention. Since no case law on this issue to-date exists in Nepal, it is yet to be seen how the court in this country would define and interpret this statutory requirement. Generally, the term novelty in the parlance of patent is understood to mean 'not previously patented, published or used' (Machlup, 1958a). Article 2(1) of the UK Patent Act 1977, for example, holds invention to be new if it does not form part of the state of the art. Definition of invention in the Patent, Design and Trade Mark Act 1936 is predicated on this notion. As a rule, a patent is deemed to be anticipated if the invention was publicly known or used by others before the applicant's date of invention.

Article 2(1) of the Nepalese act requires that an invention be 'useful' to obtain patent protection. Whether an invention is useful or not is determined by reference to the applicability of the invention for the industrial and commercial purposes. As a rule, the invention is deemed to be capable of industrial application if it can be used or made in any kind of industry (Bently & Sherman, 2009). By extension it implies that in order for an invention to be industrially applicable it must have some useful purpose. But the fact that an invention can be used or made in industry does not by itself qualify for patent protection if the use of that invention is morally offensive or injurious to the public order. In a US case, *Lowell v. Lewis*, it was held that all that the law requires [by useful invention] is (quoted from Adelman, et al., 1998):

That the invention should not be frivolous or injurious to the well being, good policy, or sound morals of society. The word "useful," therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not patentable invention. It involves ethical issues where invention of products designed for immoral purposes is denied the grant of patent protection.

The issue of utility does not arise in electrical or mechanical inventions where uses are apparent. Neither does it make much sense for such inventions that are not useful or have no market potentiality. As the cost of obtaining and maintaining patent protection is very high as compared to other forms of intellectual property rights, inventors are hardly inclined to seek patent protection for such inventions (Moore, et al., 1999). However, it has an important bearing with respect to chemical and biotech inventions where most often the researchers come across new compounds or new sequences of genes without knowing how they could be used. Patents for such inventions are not granted unless utility for them is established. Hence applications failing to disclose any function or industrial application are not awarded with patent protection (Bostyn, 1999).

But novelty and utility are not enough for an invention to be qualified for securing patent protection. The other important attribute which it must exhibit is inventive-step or non-obviousness as it is called in the United States. Patent is not awarded for any invention that does not involve inventive step beyond the prior art. Article 56 of the

European Patent Convention 1973 (Christie & Gare, 1998) states: "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."

Inventiveness is one of the most important requirements for patentability. And it is also one of the most problematic areas in deciding patent eligibility since it is hard to determine what is non-inventive (obvious) from what is inventive (non-obvious). The basic purpose of this requirement is to ensure that only meritorious inventions are granted patent protection. If patents were granted for the object or process involving a slight modification of any original invention, it would lead to an unjustifiable interference with trade (Bently & Sherman, 2009).

Nepalese law is unclear on this aspect as it is not clearly spelt out anywhere in the text. Article 5 dealing with the examination of patent application provides that the department of industry upon submission of a patent application examines whether the invention is new or not and whether it is useful to the people in general or not. Beyond these two requirements of novelty and utility which an invention must satisfy to be eligible for patent protection, there is no slightest reference to inventive step. Hence it is doubtful as to the statutory requirement for inventive step in Nepalese law. However, assuming this requirement to be implicit in the law, it is doubtful that if it was ever implemented since the department of industry does not possess requisite prior art documents and technically qualified examiner to determine inventiveness.

Article 3(1) of the Nepalese law stipulates that any person willing to have right over any patent (invention) has to register patent in his name as specified in the act. This is a basic formal requirement before a patent application can be prosecuted to obtain patent protection. Article 3(2) of the law grants the patentee the right to exclude or prohibit others from copying and using the patent without his written consent. As such, any act or use of the patent without the written authorization of the patent holder would constitute infringement of the rights therein and the person liable for such infringement may be punished under Article 11(1&2) with a fine up to approximately US \$ 7000. Articles and goods connected to the offence shall also be confiscated. Besides, the law prescribes a fine up to US \$ 300/- for those attempting to do or instigating to do any work prohibited by law.

Where a patentee has to incur a loss owing to the infringement of his/her rights, Article 25 provides that the Department of Industry may in such cases recover the appropriate amount of such losses from the infringer in the form of compensation to the patentee.

The law grants patent for a term of seven years from the date of patent registration. It can be renewed for two terms of seven-year each adding the life of patent to 21 years. This term conforms to the WTO/TRIPS requirement which is fixed at 20 years from the filing date (TRIPS Article 33). By Article 23 Kha (2), failure to renew the patent registration within the time-frame stipulated by the act shall *ipso facto* render the patent

invalid. After the expiration of this period, the subject matter covered by the patent will fall into public domain allowing anyone to use the patent without the consent of its owner.

Article 6(1) enumerates circumstances in which no patent shall be granted. Accordingly, the law denies patent in respect of (i) invention that has already been registered in the name of other, (ii) invention that is not invented by the applicant himself and he has not acquired the right therein from the inventor and (iii) invention that would cause adverse effect in health, *ordre* public or morality or national interest. In addition to these, patent shall not be granted if it violates any prevailing laws of Nepal.

As discussed earlier, rationales justifying the grant of patent protection are premised on various economic grounds. One that is often invoked in conventional discussion as well as in courts is the disclosure of invention. This view holds the grant of patent monopoly for a limited term as a reward in exchange for the disclosure of invention through the publication of patent applications and grants in the wider societal interest. Information disclosed in the patent specification enriches the public stock of technical knowledge. They constitute an important source of technological information for further invention and innovation which is critical to the economic advancement of the society. Patent in this view basically trades off the cost of rewarding the inventors with the benefit to the public of diffusion of new technical knowledge. As such patent legislation in almost all countries contains a mandatory provision for the full disclosure of the invention. This disclosure should be useful and sufficient so as to enable a person skilled in the art to perform the invention. Specifically patent specification must contain information on how to make and how to use the invention-as-claimed. In short, it should teach a person of skill in the art 'how to make the invention?' This is known as the 'enablement' requirement in the United States. The policy rationale for this requirement is that the patentee must teach his invention in return for the monopoly price the society pays for it. Second, it ensures that scope of a patent claim accords with the extent of the inventor's technical contribution (Adelman, et al., 1998).

Disclosure requirements are laid down in Article 4:1(c and d) of the Nepalese law. Article 4:1(c), for example, requires patent applicant to disclose the information regarding the process of making, operating or using the patent. The applicant must also disclose the theory or formula, if any, on which the patent is based. Such disclosures constitute valuable addition to the existing stock of technical knowledge. Information thus disclosed in the patent applications that succeed to obtain patent is published in the Nepal Gazette, an official journal of Nepal Government. In this regard, Article 7A provides that the Department shall publish all patents registered with it except those to be kept secret for national interest in the Nepal Gazette for the information of the general public. By Article 7A(2) anyone willing to see or take a copy of the statements, drawing or sketch of a patent published in the gazette may do so on payment of a prescribed fee. If anyone has any objection to such a patent, he may lodge a complaint with the Department within a period of 35 days from the date of seeing or copying the patent as provided under section 7A(3). On receipt of this complaint the Department shall take necessary action after conducting inquiries.

On the registration of foreign patents the Nepalese law maintains that the title to any patent registered in a foreign country shall not be valid unless it is registered in Nepal. However, no enquiries shall be made for registration in Nepal of such patents provided the certificate of their registration in foreign country is submitted along with the application.

There have been no radical changes in the basic format of the Nepalese patent law since 1965. Except for few changes in the form and substance of the law by way of amendment, the law is yet to take its modern form. The fact that Nepal has negligible number of case laws on patent demonstrates that the use of this law in the country is scant as there is little invention. This perhaps explains why much of the important features and details that characterize the patent law of the industrialized countries are utterly missing in Nepalese law. Need for such sophistication has not arisen since the law is invoked only now and then. It is thus unsurprising to see significant gaps in the law. Most provisions in the law are formulated in broad terms. Article 6 on non-patentability, for example, does not specify the subject matter which may not be patentable. Instead, it envisages the situations under which patent may not be granted. One could hardly predict how the court would interpret these situations given the fact that the same invention could have both 'useful' as well as 'harmful' applications. Again, the law contains no information on how the novelty, inventiveness and utility requirements for patent registration are determined. Neither does it make any reference to prior art by which novelty of the invention is ascertained. Many new developments in the frontiers of technology, such as biotechnology, genetic engineering and so on, are outside the purview of the law.

It is recalled that while these new subject matters are now occupying eminent place in trade and commerce they are at the same time posing host of issues that have social, ethical and political-economical dimensions. One of the most controversial issues that provoked widespread ethical debate in Europe and elsewhere is the patentability of human genetic material. E.U. Directive (6:2(a)), for example, considers the process for cloning human beings and use of human embryos unpatentable for reason of being contrary to *ordre public* or morality (Bostyn, 1999). Discussion on these subjects is, however, outside the scope of this paper.

Biotechnology presents both opportunity and challenge to the developing countries. The opportunity is that the application of this technology has proved most effective in the development of genetically modified agricultural crops and animal suitable to tropical climates, in developing new vaccines and antibiotics against diseases peculiar to tropical countries, and in developing genetically modified organism for environmental cleanup specially for remediating the pollution generated by over industrialization. The challenge lies in the fact that major research outputs on biotechnology such as the inventions relating to genes and proteins, the transgenic plants, the human genome are all patented in the West foreclosing these frontiers of research to new firms and researchers from the developing world (Braga & Fink, 1998; Smith, 2009).

The other side of the law is its implementation aspect and this is more important and challenging than the substantial aspects of the law because the more strong this aspect the more effective is the law. Unfortunately, this is where the least developing countries like Nepal miserably fail. The obvious reason in most cases for this failure is that essential prerequisites required for the execution of the law are not in place by the time the law is enacted. Over the time when these prerequisites come into existence many of the provisions in the law are outdated rendering the law obsolete.

The same applies to the implementation of patent law in Nepal. The necessary institution- qualified patent attorneys, trained and qualified patent examiners, and trained lawyers and judges- to support the management of effective patent regime is miserably lacking. By the time these institutions would grow and start taking root, the existing law may not be competent to deal with the emerging new reality. Hence the need arises for its reform.

In Nepal public awareness about patent is extremely low because of very little application of the law. This has further weakened the demand for the domestic use of the patent law. There are many instances where many inventors for the lack of knowledge on patent protection fell victim to illegal counterfeiting and imitation of their inventions as they rushed to commercially exploit their inventions before securing patent protection in the hope of making some profit.

By far, patent prosecution is a time-consuming and costlier exercise, involving technical expertise and services of a group of professionals – patent examiners, patent attorneys, patent lawyers, and so on. Availability of these expert services is essential before the users or clients can easily avail themselves of the law. Regrettably, these services have not developed and proliferated to the extent needed for the promotion of the patent system in the country. Neither does it appear that the Department of Industry has at its disposal a cadre of trained and qualified patent examiners to undertake the task envisaged by the law.

It is submitted that costs of patent administration are much higher than they are for other forms of intellectual property rights. The most difficult and the expensive task in the administration of patent is the examination process of patent applications. It requires highly trained and qualified patent examiners who are supposed to be up to date in the relevant fields of technology. They must have access to patent databases and libraries to determine if the invention satisfies the statutory requirements of patentability (Braga & Fink, 1998). In the context of least developing countries, such a cadre of well qualified examiners is not easy to find. Even if they are found they may demand for higher salary which may not be affordable for the government. As it is much costlier and technically demanding, the administration of patent examination may not be viable for the least developing countries in view of few patent applications they receive.

The importance or relevance of patent regime, as it holds in principle with other forms of intellectual property regime, arises with the burgeoning market for the commercial exploitation of inventions. The existence of large market leads to increasing

investment by firms on R&D to generate new and useful inventions and innovations in its bid to remain competitive in its field of technology. The core function of patent system is to protect and promote this investment. It does so by the grant of exclusive rights. These exclusive rights are the means that enable the firms to secure the return on investment. And it is this return that, in theory, induces firms to further invest. Patent system has little to do where firms are engaged in free-riding without having anything to pay for the original inventor and are thus reluctant to invest on inventive and innovative activities.

In Nepal, data for expenditure by firms on R&D is not available. Neither is the State expenditure on R&D clearly recorded. However, it is widely assumed that most firms are either imitative or involved in assembling activities. Only few are engaged in innovative activities. Results of R&D in the public sector are freely disseminated. It appears that inventions made in the public laboratories are not taken for patent registration. Record documenting the grant of patent for any invention made under public fund in the public institution does not exist. This being the case, it is believed that patent protection in Nepal has still little relevance. Data for patent registration by the Nepalese nationals till last year distinctly point to this fact.

**Table: 1 Status of Patents, Design, and
Trade Marks Registration Until July 16, 2010**

Description	Nationals	Foreign	Total
Patents	31	36	67
Design	54	19	73
Trademarks	21362	6971	28333

Source: Department of Industry.

Patent law in Nepal is still in its infancy. The law will gradually develop to maturity only when demand for patent protection raises with an increasing use of the law. However, this may not take place unless there exists a large home market in which individual firms and entrepreneurs who invest large sums on invention and innovation are able to earn profit by their commercial exploitation. And this leads to another important dimension of patent protection which is the existence of market for local invention and innovations. What actually induces local firms and laboratories for invention and innovation is the prospect of profit from the exploitation of their inventions. The larger the market the bigger is this prospect of profit. The function of patent is to protect this profit by warding off the competitors. Absence this protection, it is believed that firms will not risk their investment. As a result, inventions and innovations will not take place to the extent needed for the advancement of the society.

Costs and Benefits of Patent Protection

Patent protection has costs as well as benefits. The cost it entails is a social welfare loss resulting from the grant of monopoly for a fixed term. The benefit it offers is the rapid disclosure of new knowledge and promotion of investment in research and development and the promotion of new and valuable technological innovations leading to

the faster economic growth. Since these valuable technological innovations may not take place in the absence of patent protection, it is believed that benefits accruing from the grant of patent far outweigh its cost. Accordingly, patent is often justified in the advanced countries by reference to this cost and benefit. Argument of this sort is mainly based on economic consideration. There is also moral, natural right premise that is often invoked to justify the right of the inventors to their inventions.

As international trade and commerce came to be increasingly dominated by technological rivalry with the growing share of knowledge-intensive products patent has come to assume foremost prominence in the developed countries especially since the second half of the twentieth century. The number of worldwide annual grants of patents increased two-fold from 320,000 in 1981-82 to 670,000 in 1994-95 (Braga & Fink, 1998). Patent regime is now promoted in First World countries as a policy instrument in pursuit of technological lead for achieving faster economic growth. For them, intellectual property regime is a crucial factor in their prosperity. This however is not the case in Third World countries. Patent does not play the same role in the economies of these countries as it does in the economies of industrialized countries. Patents in the least developed countries like Nepal are not still valued so much for the lack of research and development activities and local capacity to develop patentable products and processes. In their absence, the developing countries have no incentives to strengthen patent protection which virtually functions as an instrument to shift rents to foreign innovators at the expenses of local consumers and producers (Konan, et al., 1995). Hence the establishment of strong patent regime in these countries does not have much relevance from their short term national interest perspective. It largely helps to serve the rent-seeking interest of the technology exporting countries of the West at the cost of sacrificing some of the basic needs of these technology importing countries. Third World countries are therefore inclined to take the view that intellectual property system is a "kind of new protectionism compensating for declining forms of trade protection such as tariffs, non-tariff measures and subsidies" (WIPO, 2004).

The point here is that the relative costs and benefits of patent regime vary across the countries depending upon the level of economy; particularly the capability to generate intellectual property. Evidences, for example, indicate that countries where this capability is high tend to gain more from the creation of strong patent regime. By contrast, countries where this capability is severely lacking and which have little to protect of their own intellectual property tend to loss. As stated earlier, this loss, among other factors, is due to the fact that the patent regime in these countries is mainly used to serve the function of collecting royalties from their own people for the use of imported technology and remitting these to the owners in the exporting countries.

This in essence means patent system is inclined to favor a country that is able to generate enough intellectual property. The reason perhaps is that the system of intellectual property rights is originally designed to protect the interest of those who produce intellectual property. It has very little, if any, to do with those that are not able to generate intellectual property. Hence the interests and problems of the countries which

are the net importers of intellectual property rights are the matters to which intellectual property systems are less concerned with. It is submitted that intellectual property system is simply the means not an end in itself. It only helps reap the benefit from the creation of intellectual property. It has little to offer to those lacking the ability to create. This means it helps those who help themselves to generate intellectual property.

The discussion above makes it clear that a least developing country like Nepal may not gain from the establishment of strong patent regime. Whatever it could gain in the short run is too little to offset the losses which it has to suffer on account of various reasons. Braga (2000), for example, lists some of these gains and losses to a least developing countries from a reform designed to increase intellectual property rights protection. The foremost social gains according to him are (a) cost savings associated with new technologies developed by additional R&D and by the disclosure of new knowledge; (b) cost savings associated with technological transfers that could only occur under the more strict intellectual property rights protection; (c) additional investment fostered by the new regime of protection; and (d) higher quality products becoming available for consumption. Against these benefits the losses entailed by enhanced intellectual property rights protection are (a) increase in royalty payments to foreigners being net importers of technology, (b) displacement of firms devoted to piracy, (c) opportunity cost of additional domestic R&D; (d) the eventual loss of consumer surplus due to higher prices resulting from the monopolization; and (e) costs of establishing an effective, intellectual property system.

However, the question of adopting a tighter protection is a matter to be determined by the development of an overall economy. The critical question, as Konan, et al. (1995) posed, is not whether a country will strengthen intellectual property rights, but when it will do so. The obvious answer is that need itself dictates it as a country reaches a certain level of development acquiring certain level of technological capability. Stated simply, a country would find adherence to tighter protection system in its favor when it is obliged to adopt it to protect the interest of its own domestic firms and industry. And this occurs, as stated above, at a certain point of development. Until the economy takes off at this point, it is simply difficult for the economy of these countries to sustain tighter IP protection, especially patent protection. Referring Helpman's study, Konan, et al. (1995) conclude that "as long as innovation occurs in the developed country, and the developing country absorbs technology either by imitation or investment, the developing country never gains from strong IPRs."

Viewed from the perspective of political economy in the post-TRIPS environment it is not all that easier as it was before the TRIPS for the newly independent and least developing small countries to develop their capability in the technical field. It is simply because the opportunity to develop by imitation is now largely foreclosed by the TRIPS. Switzerland and the Netherlands went without patent system for a long time towards second half of the nineteenth century. As their case amply demonstrates, they could however significantly develop their technical capability largely because they were then free to imitate the technologies that were developed in their neighboring countries. Later

when their technologies were freely imitated by others they were obliged to re-introduce patent regime more by the need to protect and promote the interest of their own domestic industries than by any desire to protect the interest of foreign inventors. The crux of this discussion is that the post-TRIPS period is likely to see greater reliance of the small least developing countries on the imports from the developed countries to meet their need in the technical field. This in essence means a gap that now exists between the 'haves' and 'have-nots' will widen further and further. In this new environment, the intellectual property system with its inherent benefits to those creating and developing the ideas into a marketable object and its universalisation through the TRIPS Agreement could be the most convenient instrument for the owners of intellectual property in the North to gradually sabotage the economy of these small newly independent countries, the so-called least developing countries, to the brink of their collapse. It is the thought of this situation that gives rise to the apprehension of economic colonization of these countries by the North in the twenty-first century. Given the prevailing situation of most of these countries – political instability, fragile economy and poor governance – it is but hard to refute this apprehension.

IP Institutions

Protection of intellectual property rights is one of the essential pre-conditions for the overall cultural and industrial development of the country. Specifically, the need for this protection arises with the growth in the capability of the country to generate intellectual property. The effective protection of IP rights presupposes the existence of well-developed intellectual property institutions. Such institutions include IP laws and rules, enforcement mechanisms and agencies such as courts and tribunal, networks, IP lawyers and attorneys, knowledge based organizations, collective management organizations and various kinds of IP related professional organizations representing writers, publishers, film producers and so on. These agencies, like the core sectors of the economy, are now viewed as the development institutions in view of their growing importance in the knowledge economy.

The institutions of intellectual property rights in Nepal are very weak. They require adequate human and capital resources to promote and exploit them to their optimum level. Laws and rules are there but they still require revision to update and standardize them. Legal experts on patent law are lacking. So is the expertise needed for the drafting of the law. It is thus difficult for the least developing countries even to evaluate the suitability of model international laws to local, economic, social and cultural conditions. It was reported that from 1996 to 2000, the International Bureau of WIPO prepared 214 draft laws on intellectual property for 19 developing countries. Over the same period, the Bureau commented or drafted amending provisions for 235 draft laws received from 134 developing countries (Drahos, nd.).

Enforcement institutions are not well developed. IP cases require prompt action. Unfortunately expecting such action from the police, the customs and the judiciary is still frustrating. Skills and competence needed to manage IP and to leverage its influence are

utterly lacking both at the government and non-government level. Awareness about intellectual property rights is very low. This awareness could perhaps dramatically rise if the owners of IP rights were aggressive to assert their rights against any violation of their rights. But the irony is that most IP rights owners do not see it paying to go for litigation in view of time, effort, and cost unless the circumstances compel them to do so.

Conclusion

Patent regime in Nepal is not likely to have any favorable impact on the economy in the foreseeable future as long as local capacity to innovate does not significantly raise and the size of the market does not expand to the extent in which new inventions and innovations can be developed for their commercialization. These in fact are the basic preconditions to which the benefits of patent protection are tied up. Arguably, until this occurs patent protection may not be favorable from the national perspective. However, given the prolonged transition in the country, there is little to hope at the moment that any genuine effort will be made to the development of these preconditions. Enacting a good piece of legislation embodying higher world-class standard has no relevance where local capacity to benefit from the provisions of that law does not exist. In want of this capacity copying the institutions and procedures developed by industrial countries over several decades may be frustrating. Such a model would backfire the very purpose of legislation as it would most likely to serve not the interest of the legislating countries but that of the countries from which it was borrowed wholesale.

The purpose of any reform in the patent law is to maximize the benefits from its protection. And this benefit may not be ensured where the provisions in the law stand far from the ground realities of the local need for protection. Focus should therefore be entirely concentrated on building the capacity before opting for strong regime of patent protection. And this necessarily requires promoting research and development, education and other such activities that would significantly enhance the development of local capability for inventions and innovations. Patent legislation should be updated and its standard gradually upgraded along with the increasing capability of the local inventors and firms in order to enable them to take benefit from their creations. This equally applies to other forms of intellectual property, such as copyright.

As the foregoing discussion points up the strong patent regime is neither favorable nor desirable to the country at present. The patent law that is now needed by the country is the one that is flexible enough to meet the country's treaty obligation (such as the TRIPS Agreement) and at the same time that takes account of the present need and capacity of the country without being obstacle to the promotion of local invention and innovation. The interest of those who invent and invests on its commercialization must by any means be protected to ensure that invention and innovation, the building blocks of modern knowledge-based economy, keep on continually growing. In short, the law should seek to balance a trade off between present and future need of the country. The present need demands that certain level of laxity should be allowed for the industries that have survived on imitation while the future need dictates that any such leeway would damage

the prospect for investment and innovation as the proliferation of imitation and free-raiding would take away the incentives for the firms and individuals to invent and invest on its commercialization. And this certainly is a difficult choice before the policy makers.

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