

Towards greater IPR protection

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The "gulf" has always been "wide open" for Indian "workers". The slow but steady emergence of the "gulf states" into technology-plus manufacturing and service industry location has now opened up brighter opportunities, not only for "knowledge workers", but also for the "knowledge-based industries" to relocate, especially when problems of over-regulation on domestic front tend to slow down or stagnate the growth and investment opportunities in R&D which is the lifeline of knowledge-based industries like pharma.

The gulf countries are emerging as preferred industry destinations for very good reasons. Arbitrariness and adhocism have been consigned to history by the gulf regulators. The emergence of the Gulf Co-operation Council (GCC) as an economic and political policy coordinating forum for the six member states (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the UAE) has contributed substantially to improve investor confidence and attract long-term FDI in "knowledge-based" industries. Another alluring ingredient is "infrastructure par-excellence", meeting not only current needs but future expectations.

On the micro level, the regulatory reforms undertaken by the GCC has substantially helped enhance the comfort levels of investors. The pharma industry is acknowledged to be regulatory intensive. The pharma regulatory scenario in gulf countries have largely been based on the USFDA model but with case-to-case treatment criteria. With the emergence of GCC and well-trained regulatory teams in place, the pharma regulations have also become effective and predictable in procedures and results.

Trade policies, documentation requirements, technical standards and Intellectual Property Rights (IPR) protection are all evolving to meet the WTO harmonization levels. What attracts investors to gulf countries most is the fact that there is a strong will to perform to perfection in every field undertaken by UAE and other gulf states.

The GCC countries are in varying stages of implementation of TRIPs, Patent Laws and other IP Laws. Saudi Arabia is yet to become a member of WTO. However, all gulf countries are members of WIPO (World Intellectual Property Organization). In recent years substantial progress has been made to adopt the IPR laws and regulations consistent with WTO and complying with TRIPs (Trade Related Intellectual Property Rights).

The progress made by GCC in the field of patent laws is commendable. GCC has issued a practicable IP/patent law aimed at creating a patent system for all member states. Eventhough the GCC Patent Law is labeled (by developed countries) as not fully TRIPs-compliant, the pharmaceutical patent regulations can safely be appreciated as Doha-compliant and well-balanced between the national public health and nutrition needs and

the private rights of the inventor.

The Federal Law No.(17) of 2002 pertaining to Industrial Regulations and Protection of Patents, Industrial Drawings and Designs of UAE has been adopted by the GCC members also. Incidentally, UAE is a federation of seven emirates (Abu Dhabi, Dubai, Sharjah, Ajman, Umm Al- Quwain, Fujairah and Ras Al-Khaima).

The UAE has repealed the previous outdated copyright, trade marks and patent laws and issued an improved legislation as above to meet the high levels of protection bilaterally desired by the USA. The UAE Patent Law is unique in that UAE provides de facto patent protection for a number of US patent protected medicines. Pharmaceuticals introduced in UAE which are patent protected in USA under USPTO, automatically becomes eligible for patent protection in UAE on the basis of the Orange Book listed patents supporting the dosage form.

Patents in UAE

The UAE Patent Law provides patent protection for an invention which is defined as "any Innovative idea relating to a product, a method of manufacture or an application of a known method of manufacture leading to a practical solution to a technological problem". This makes patenting in UAE a "pleasure" even for small and medium (SME) sector pharmaceutical companies from India. UAE grants invention patents (Letter Patents) as well as utility patents (Petty Patents) where there is no invention.

Even though, the definition of invention in the UAE Patent Law is neither TRIPs compliant (in the literal sense) nor comparable with definitions in Indian and other overseas Patent Laws, many of the UAE provisions are comparable to Indian Patent Law. UAE has become a member of PCT (Patent Cooperation Treaty) and has made provisions for filing of international applications and/or national phase applications based on PCT applications. National treatment as well as transitional arrangements are provided under Article 2 and 3 respectively. While unity of invention is a requirement, lack of unity of invention will not negate a grant of patent (which means that the divisional facility will be relied on).

Similar to provisions of Section 3 "inventions not patentable" in (Indian) Patent Act, 1970 (as amended), the UAE Patent Act provides under Article 6 that the following are not patentable.

- 6(1) (a) Plant varieties, animal species, or biological methods of producing plants or animals. Exceptions shall be allowed for the microbiological methods and their products.
- (b) Diagnostic methods, treatments and surgical operations needed for humans and animals.
- (c) Scientific and Mathematical principles, discoveries and methods.
- (d) Guides, rules or methods followed to conduct business or perform mental activities or play games.
- (e) Invention that may lead to violation of the public order or morals.

Similar to Sec. 4 of Indian Patent Act Art.6(2) provides that patent applications for inventions related to National Defense, will be dealt through separate implementing

regulations.

A few provisions are interesting and especially unambiguous. Employer will automatically become the owner of all inventions by the employee. However, if invention is extraordinary, the employer will need to give additional compensation to the employee. Further, these provisions have some chrono-limitations, i.e. there are some timely notices and procedural formalities to be fulfilled. Priority provisions with (upto 12 months grace period) is provided.

Provision for opposition, post acceptance/ publication within six months is available. Six months time is available for payment of annuities for maintenance. Patentee rights are TRIPs compliant. A provision under Article 17 is unique and similar to Indian Patent Act provision under Sec. 11A(7). If an entity or a person is already manufacturing a product in UAE, using a patented process or involving a patented product in UAE, prior to grant of a patent in UAE, the manufacturer can continue without fear of infringement. Academic research exemption [Art. 19(1)] as well as temporary transit exemption [19(2)] are available. The latter exemption is exemplary, which is not available in similar domains like Singapore.

Compulsory licencing provisions (Section Two; Article 24) are extensive and are subject to minimum "three years after grant" limitation and also subject to fair compensation (royalty) and other terms. However, these limitations of time and royalty can be overlooked or disregarded in case of national emergency, urgent public need or if intended for non-commercial purposes. The terms are well defined and the minister is the authority equivalent to patent controller in India. PCT application related provisions are clearly incorporated. There are independent provisions for "know-how" as well as for recording assignments. A separate Chapter Four is available for "Contractual Licenses".

In conclusion, the IP/Patent Laws of UAE are comprehensive, well-defined and mostly TRIPs compliant. However, the implementation and the procedures in a uniform manner will put these provisions to test.

Overall the scenario of intellectual property protection in UAE/GCC appears attractive and conducive. There are few senior Indian pharma MNCs well- entrenched in the gulf countries. There are also a few NRI owned manufacturing facilities. Ultimately, it is the experience of these players in the market place which will put the "proof of the pudding to taste".

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