National Policy for Intellectual Property in the Field of Healthcare

Introduction:

"Invention is any new discovery or innovation usable as an industrial product, whether such discovery or innovation is related to new industrial products or to the novel methods and means or both."

Pharmaceutical patent is one of the most important practical applications of industrial intellectual property, whether in terms of the nature of privileges conferred on drug inventors or those who reserve the rights of such medicines, or in terms of the means of protection legally prescribed for these privileges. An evidence of this can be found in all laws related to industrial property or intellectual property in general, which have reviewed, in which pharmaceutical patents are given special attention and a significant portion of legal requirements is allocated thereto, placing such patents at the top in terms of industrial property requirements.

Pharmaceutical patent undoubtedly helps understanding the successful means to protect patents and preserve the rights arising therefrom. Pharmaceutical patent is a safety valve for its holder, as it represents a license and a bond that entitles its holder to confront the pharmaceutical companies that violate the pharmaceutical patent holder's rights, conferred on by virtue of such patent. Meanwhile, holder shall have such exclusive rights to throughout drug patent protection period, which means that this type of protection applies to the medical products, as they are the result of a human effort, where an innovator created something that had no physical existence.

Therefore, patent protection is a key element for the protection of the rights of drug innovators, medical products and scientists, as this patent is a certificate proving the rights of innovators in terms of the medicines they have invented and tested. Further, it serves as a supporting bond that institutions use to prevent third parties to violate their rights, which entitles them to claim for damages in the event a violation thereto has occurred. Intellectual property involves unlimited moral rights, which requires protection; internally through national laws and externally through international conventions and agreements against any financial exploitation of the same without a permission of its holder or causing moral damages to its holder by attributing such patent to others.

Intellectual property rights are divided into several types, such as moral, artistic and scientific property rights, which are a number of thoughts, views, and products of the mind, imagination, art and all other designs of intellectual or mental creativity. Industrial property is a number of industrial drawings, designs, patents, invention privileges and drawings. Whereas commercial property is a number of physical and moral elements allocated for a practicing a commercial profession in general, along with shares, trademarks, commercial names and brands.

Intellectual property rights are given a great significance when developing the international and national policies, in legal, healthcare, social and cultural spheres. Intellectual property rights have become a key focus in inter-state commercial and cultural relationships, as they implicate critical economic and technical effects, which led several entities to consider means to provide legal protection, such as patents.

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The development of legal rules and provisions that recognize intellectual property rights is not sufficient, rather, it is necessary to establish an effective and prompt mechanism to ensure the implementation of such laws and the enforcement of these rights in favor of their holder by the competent authorities (internationally and locally), thus ensuring that violation of these rights is repelled by all means and methods.

The concept of intellectual property is not a novel concept. It is believed that the intellectual property system was sparked in Italy in the Renaissance Period. At the end of nineteenth century, several countries considered the adoption of laws regulating intellectual property. Internationally, two conventions were signed as a global basis for intellectual property, namely: Paris Convention for the Protection of Industrial Property, 1883, and Berne Convention for the Protection of Literary and Artistic Works, 1886.

International Organizations

World Intellectual Property Organization (WIPO): World Intellectual Property Organization was established in 1967, with its permanent headquarters in Geneva. WIPO is an agency of the United Nations and was created with the aim to promote and protect intellectual property across the world.

World Trade Organization, 1994: The organization adopted Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement Annex 1C.

It is worth noting that the United Arab Emirates is a member of the two organizations and party of TRIPS as well.

Analysis of the Current Status:

Scope of Intellectual Property Protection in the UAE:

First: Protection before issuance of Federal Laws:

Emirati legislation lacked any intellectual property protection laws until 1992, as the UAE was adopting general rules of damages, principles of equity and justice, and Federal Law No. (4) of 1979 on Repression of Fraud and Deception in Commercial Transactions.

Second: Protection after issuance of Federal Laws:

By 1992, several laws were issued by the UAE regulating intellectual property rights:

Federal Law No. 37 of 1992 on Trademarks (The entity in charge of trademark registration is Ministry of Economy, represented by Patent Office).

Federal Law No. 40 of 1992 on Protection of Intellectual Works and Copyright, regulated by Ministry of Culture.

Federal Law No. 44 of 1992 on Regulation and Protection of Industrial Property of Patents, Drawings and Designs.

The UAE joined and approved several international conventions on intellectual property, including, but not limited to:

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- Federal Decree No. 21 of 1975 on approving UAE to become a member of World Intellectual Property Organization.
- Federal Decree No. 65 of 1981 UAE on approving Constitution of the United Nations Industrial Development Organization.
- Federal Decree No. 84 of 1984 on approving UAE to become a member of Convention of Cooperation on Patents.
- Federal Decree No. 20 of 1996 on approving UAE to become a member of Paris Convention for the Protection of Industrial Property.
- Federal Decree No. 21 of 1997 on agreement and protocol for UAE to become a member of World Trade Organization and Uruguay Round Final Act.

As a result of UAE joining most of the conventions regulating intellectual property rights and becoming a member of such international conventions and treaties, it was necessary for the UAE to review its laws to be in line with the obligations arising from such conventions. Some of these laws were amended and others were revoked as follows:

- Amendment of Federal Law No. 37 of 1992 on Trademarks by Law No. 19 of 2000 and Law No. 8 of 2002.
- Revocation of Federal Law No. 40 of 1992 on Protection of Intellectual Works and Copyright, by Federal Law No. 7 of 2002 on Copyrights and Related Rights.
- Revocation of Federal Law No. 44 of 1992 on Regulation and Protection of Industrial Property of Patents, Drawings and Designs, by issuance of Federal Law No. 17 of 2002 on Regulation and Protection of Industrial Property of Patents, Drawings and Designs.

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Alignment with UAE Vision 2021

National Policy for Intellectual Property in the Field of Healthcare is in line with UAE Vision 2021. The Vision aims to make the UAE among the best countries in the world by the Golden Jubilee of the Union, through several elements, most importantly are achieving a world-class healthcare system, transforming into knowledge economy, through promoting innovation, research and development, as well as strengthening the regulatory framework for the key focus sectors of the UAE.

Alignment with Strategy

This Policy is covered under Strategic Theme of Ministry of Health and Prevention (MOHAP) Strategy 2014-2016: To enhance individual and community health by providing comprehensive, innovative, and fair healthcare services in sustainable healthy environment through the development and enforcement of healthcare policies and legislation, with the participation of public and private sectors.

Concerned Partners:

- MOHAP's concerned departments
- Dubai Health Authority
- Department of Health – Abu Dhabi
- Sharjah Healthcare Authority
- Ministry of Cabinet Affairs and the Future – Healthcare Policy Management
- Ministry of Interior
- Ministry of Economy
- Ministry of Foreign Affairs and International Cooperation
- Federation of UAE Chambers of Commerce and Industry
- Emirates Intellectual Property Association

Vision

To promote the development of the healthcare sector by ensuring the protection of intellectual property rights in the field of healthcare and using the same as a means to encourage and cultivate creativity and innovation.

Scope of Policy

Medical products (all medicines, medical devices, or healthcare products) and medical research.

Definition of Intellectual Property:

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Creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.

Intellectual property is protected in law by, for example, patents, copyright and trademarks, which enable people to earn recognition or financial benefit from what they invent or create. By striking the right balance between the interests of innovators and the wider public interest, the intellectual property system aims to foster an environment in which creativity and innovation can flourish.

Objectives of Policy:

To set a national multi-sector timeframe to enhance the rules and standards of intellectual property in healthcare field.

Key Themes:

The key themes to which concrete actions must be taken to promote intellectual property policy in healthcare field within the UAE:

- Encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the research and development needs of the UAE, protects public health and promotes access medical products to and medical devices, including medicines for all;
- Identify and promote the proper solutions for local issues related to intellectual property in healthcare field;
- Manage the intellectual property;
- Increase appreciation for innovators, creators and scientists;
- Protect all forms of healthcare knowledge and medical research conducted within the UAE, and using such knowledge to prevent diseases and enhance community health and wellbeing;
- Facilitate transfer of technology for prompt advancement of the UAE;
- Encourage using and accessing available information and technology to promote scientific research and innovation;
- Provide an assessment of the public health needs of with respect to diseases that disproportionately affect the public health and identify their research and development priorities at the national level;
- Raise awareness of intellectual property rights in the healthcare field; and
- Build and improve innovative capacity for research and development.

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Elements of National Policy for Intellectual Property in the Field of Healthcare

Element 1. Prioritizing Research and Development Needs

UAE's health needs must be addressed and disease-related research gaps need to be identified urgently to drive sustainable research and development on new and existing products.

The actions to be taken to prioritize research and development needs are as follows:

1. mapping national research and development activities with a view to identifying gaps in research and development on diseases that disproportionately affect public health through developing methodologies and mechanisms to identify and assess such gaps;
2. formulating explicit prioritized strategies for research and development at the national level;
3. include research and development needs on health systems in a prioritized strategy; and
4. increase overall research and development efforts on diseases that disproportionately affect the public health, leading to the development of quality products and that are user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability).

Element 2. Promoting Research and Development

Development of health research policy, as a range of measures to promote, coordinate and finance public and private research in the UAE needs to be substantially enhanced.

The actions to be taken to promote research and development are as follows:

1. supporting institutions to develop or improve national health research programs and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area;
2. promote cooperation between private and public sectors on research and development;
3. provide support for national health research programs where feasible and appropriate;
4. support discovery science, including, where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products;
5. promote and improve access to compound libraries through voluntary means, provide technical support and promote access to drug leads identified through the screening of compound libraries;
6. identify incentives and barriers, including intellectual property-related provisions that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools;
7. support early-stage drug research and development;

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8. build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international and national ethical standards;
9. promote the generation, transfer, acquisition upon agreed terms and voluntary sharing of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems;
10. improve cooperation, participation and coordination of health and biomedical research and development;
11. promote greater access to knowledge and technology relevant to meet public health needs;
12. promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centers;
13. promote public access to the results of government-funded research by strongly encouraging all investigators funded by governments to submit to an open access database an electronic version of their final, peer-reviewed manuscripts;
14. support the creation of voluntary open databases and compound libraries, including voluntary provision of access to drug leads identified through the screening of such compound libraries;
15. encourage the further development and dissemination of publicly or donor funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs;
16. consider, where appropriate, use of a "research exception" to address public health needs consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights.
17. establish and strengthen national and regional coordinating bodies on research and development; and
18. facilitate the dissemination and use of research and development outcomes.

Element 3. Building and Improving Innovative Capacity

There is a need to frame, develop and support effective policies that promote the development of capacities related to health innovation in the UAE. Key areas for investment are capacities relating to science and technology, local production of pharmaceuticals, clinical trials, regulation, intellectual property and traditional medicine.

The actions to be taken to build and improve innovative capacity are as follows:

1. support existing and new research and development institutions;
2. strengthen health surveillance and information systems;
3. framing, developing and supporting effective policies that promote the development of capacities for medicine innovation;
4. strengthen human resources in research and development in the UAE through long-term national capacity-building plans;

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5. encourage international cooperation to develop effective policies for retention of health professionals, including researchers of pharmacology;
6. develop successful health innovation models in developing innovative capacity in pharmaceuticals;
7. developing and implementing, where appropriate, possible incentive schemes for health-related innovation; and
8. encourage recognition of innovation for purposes of career advancement for health researchers.

Element 4. Transfer of Technology

Development cooperation, partnerships and networks between Emirates need to be supported in order to build and improve transfer of technology related to health innovation in a manner conducive to social and economic welfare, and to the balance of rights and obligations.

The actions to be taken in relation to this element are as follows:

1. explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development;
2. promote transfer of technology and production of health products in the UAE through identification of best practices, investment and capacity building;
3. encourage inter-state cooperation for technology transfers, and collaboration between institutions and the pharmaceutical industry;
4. facilitate local and regional networks for collaboration on research and development and transfer of technology;
5. promote the necessary training to increase absorptive capacity for technology transfer; and
6. develop possible new mechanisms to promote transfer of and access to key health-related technologies.

Element 5. Application and management of intellectual property to contribute to innovation and promote public health

MOHAP must take appropriate local actions.

The actions to be taken are as follows:

- identify patents;
- develop specific rules for patent registration according to the international agreements;
- distribute roles and responsibilities between the concerned parties (MOHAP and Ministry of Economy);
- determine the approved patents through MOHAP based on: composition (active ingredient) – method of manufacture – medical declarations to be provided;

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- form and activate the role of Grievances Committee in intellectual property-related disputes in the field of healthcare, as MOHAP must have a representative member of such committee;
- implement and adhere to the timeframe of international agreements;
- develop a methodology for classification of medicines;
- review and update laws in proportion to keep abreast of changes in the UAE in terms of medicines;
- create a database for medicines and health products related patents, along with details of such patents;
- raise awareness;
- data exclusivity;
- Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement prohibited this through granting protection of medicine to the inventor.

If a product is patented, only the patent holder may make, use, offer for sale, sell or import that product; even if such product was composed in another method. The product becomes the exclusive property of the inventor and no other party may violate this by any of the above actions throughout the entire 20-year protection period.

1. support information sharing and capacity building in the application and management of intellectual property;
2. encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights and other WTO instruments related to that agreement;
3. promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of the UAE;
4. facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases that contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents;
5. stimulate collaboration among pertinent national institutions and relevant government departments (MOHAP and Ministry of Economy), in order to promote information sharing relevant to public health needs; and
6. promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs.

Development of Rules:

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Consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights.

Element 6. Improving Delivery and Access (International Agreements)

Mechanisms to regulate the safety, quality and efficacy of medicines and other health products, coupled with adherence to good manufacturing practices and effective supply chain management, are critical components to be developed.

1. International agreements that may have an impact on access to health products in the UAE need to be regularly monitored with respect to their development and application. Any flexibilities in such agreements that would permit improved access need to be considered for action by national authorities in the light of the circumstances. The impact of such actions on innovation needs to be monitored.
2. encouraging increased investment in the health delivery infrastructure and financing of health products in order to strengthen the health system, taking into account rational use of medicines;
3. establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices:
4. comply with good manufacturing practices for safety standards, efficacy and quality of health products;
5. make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights, in order to promote access to pharmaceutical products;
6. take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States;
7. promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, including good clinical practice guidelines;
8. support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for evaluation and approval of medicines;
9. support the production and introduction of generic versions, in particular of essential medicines through the development of national legislation and/or policies that encourage generic production and entry, including a "regulatory exception" or that are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement;
10. frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements;

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11. consider, where appropriate, inter alia, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access;
12. encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products;
13. consider the development of policies to monitor pricing and to improve affordability of health products;
14. take appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products;
15. increase information among policy-makers, users, doctors and pharmacists regarding generic products; and
16. secure and enhance sustainable financing mechanisms through:
    - document and disseminate best practices in public–private and product development partnerships;
    - develop tools for periodic assessment of performance of public–private and product development partnerships;
    - support public–private and product development partnerships and other appropriate research and development initiatives in the UAE.

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