



## Rethinking the Role of Intellectual Property Rights in Pharmaceutical Industry of Saudi Arabia

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This article attempts to analyze the role of pharmaceutical industry intellectual property rights and comparison of Saudi Arabia with other watch list and non-watch list countries according to the US trade representative Special 301 Report. Time series data (2001-2020) is used to compare and analyze the data using simple regression. Also, Covariance analysis and least square method are used to compare the data of other countries with Saudi Arabia. It was found that there is significant impact of the Saudi pharmaceutical industry on the GDP, and it has also developed its IPRs, patents, trademarks, and trade secrets. Macroeconomic outcomes are strongly tied to the enforcement of IP laws in both watch list and non-watch list countries. Therefore, it is important to underline the differences in IPR in these countries. This will help us to test whether empirical results at macro-level -that are alleged to be led by the stronger or weak IP laws – hold in the actual IP Law enforcements. In this paper, we investigate the differences and similarities in IP laws in these selected countries.

**Keywords:** Pharmaceutical Industry, Intellectual Property Rights, GDP, IP Laws, Special 301 Report, Watch-List, Non-Watch-List Countries, Patents, Trademarks, National Transformation Program (NTP) 2020

### Intellectual Property

Intellectual property consists of any original creation of human intelligence, whether artistic, technical, or scientific creation. Intellectual property rights relate to the legal rights given to the creator to protect his invention for a particular period. It is a well-known fact that IP play a very important role in the modern economy. There has been a significant increase in investments required for new technology in the markets.

The stakes of the developers of technology have become very high, and hence, the need to protect the knowledge from unlawful use has become expedient, at least for a period, that would ensure recovery of the R&D and other associated costs and adequate profits for continuous investments in R&D.<sup>1</sup>

IPR is a strong tool, to protect investments, time, money, effort invested by the inventor/creator of an IP, since it grants the inventor/creator an exclusive right for a certain period for use of his invention/creation. Thus IPR, in this way aids the economic development of a country by promoting healthy competition and encouraging industrial development and economic growth. Present review furnishes a brief overview of IPR with special emphasis on pharmaceuticals.

### Nature of Pharmaceutical Industry

The race to unlock the secrets of human genome has produced an explosion of scientific knowledge and spurred the development of new technologies that are altering the economics of drug development. Biopharmaceuticals are likely to enjoy a special place and the goal will be to have personalized medicines, as everyone will have their own genome mapped and stored in a chip. Doctors will look at the information in the chip(s) and prescribe accordingly. The important IP issue associated would be the protection of such databases of personal information. Biotechnologically developed drugs will find more and more entry into the market. The protection procedure for such drug will be a little different from those conventional drugs, which are not biotechnologically developed. Microbial strains used for developing a drug or vaccine needs to be specified in the patent document. If the strain is already known and reported in the literature usually consulted by scientists, then the situation is simple. However, many new strains are discovered and developed continuously, and these are deposited with international depository authorities under the Budapest Treaty. While doing a novelty search, the databases of these depositories should also be consulted. Companies do not usually go for

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publishing their work, but it is good to make it a practice not to disclose the invention through publications or seminars until a patent application has been filed.<sup>2</sup>

While entering an R&D alliance, it is always advisable to enter into a formal agreement covering issues like ownership of IP in different countries, sharing of costs of obtaining and maintaining IP and revenue accruing from it, methods of keeping trade secrets, accounting for IP of each company before the alliance and IP created during the project but not addressed in the plan, dispute settlements. It must be remembered that an alliance would be favorable if the IP portfolio is stronger than that of concerned partner. There could be many other elements of this agreement. Special attention will have to be paid towards maintaining confidentiality of research.

The current state of the pharmaceutical industry indicates that IPR are being unjustifiably strengthened and abused at the expense of competition and consumer welfare. The lack of risk and innovation on the part of the drug industry underscores the inequity that is occurring at the expense of public good. It is an unfairness that cannot be cured by legislative reform alone. While congressional efforts to close loopholes in current statutes, along with new legislation to curtail additionally unfavorable business practices of the pharmaceutical industry, may provide some mitigation, antitrust law must appropriately step in.<sup>3</sup> While antitrust laws have appropriately scrutinized certain business practices employed by the pharmaceutical industry, such as mergers and acquisitions and agreements not to compete, there are several other practices that need to be addressed. The grant of patents on minor elements of an old drug, reformulations of old drugs to secure new patents, and the use of advertising and brand name development to increase the barriers for generic market entrants are all areas in which antitrust law can help stabilize the balance between rewarding innovation and preserving competition.

Traditional medicine dealing with natural botanical products is an important part of human health care in many developing countries and in developed countries, increasing their commercial value. The world market for such medicines has reached US \$ 60 billion, with annual growth rates of between 5% and 15%. Although purely traditional knowledge-based medicines do not qualify for patent, people often claim so. Researchers or companies may also claim

IPR over biological resources and/or traditional knowledge, after slightly modifying them. The fast growth of patent applications related to herbal medicine shows this trend clearly. The patent applications in the field of natural products, traditional herbal medicine and herbal medicinal products are dealt with own IPR policies of each country as food, pharmaceutical and cosmetics purview, whichever appropriate. Medicinal plants and related plant products are important targets of patent claims since they have become of great interest to the global organized herbal drug and cosmetic industries.<sup>4</sup>

### **Management of Intellectual Property in Pharmaceutical Industries**

More than any other technological area, drugs and pharmaceuticals match the description of globalization and need to have a strong IP system most closely. Knowing that the cost of introducing a new drug into the market may cost a company anywhere between \$ 300 million to \$1000 million along with all the associated risks at the developmental stage, no company would like to risk its IP becoming a public property without adequate returns. Creating, obtaining, protecting, and managing IP must become a corporate activity in the same manner as the raising of resources and funds. The knowledge revolution, which we are sure to witness, will demand a special pedestal for IP and treatment in the overall decision-making process.

Competition in the global pharmaceutical industry is driven by scientific knowledge rather than manufacturing know-how and a company's success will be largely dependent on its R&D efforts. Therefore, investments in R&D in the drug industry are very high as a percentage of total sales; reports suggest that it could be as much as 15% of the sale. One of the key issues in this industry is the management of innovative risks while one strives to gain a competitive advantage over rival organizations. There is high cost attached to the risk of failure in pharmaceutical R&D with the development of potential medicines that are unable to meet the stringent safety standards, being terminated, sometimes after many years of investment.<sup>5</sup>

It is understood that the documents to be submitted to regulatory authorities have almost tripled in the last ten years. In addition, regulatory authorities now take much longer to approve a new drug. Consequently, the period of patent protection is reduced, resulting in

the need of putting in extra efforts to earn enough profits. The situation may be more severe in the case of drugs developed through the biotechnology route especially those involving utilization of genes. It is likely that the industrialized world would soon start canvassing for longer protection for drugs. It is also possible that many governments would exercise more and more price control to meet public goals. This would on one hand emphasize the need for reduced cost of drug development, production, and marketing, and on the other hand, necessitate planning for lower profit margins to recover costs over a longer period. It is thus obvious that the drug industry must wade through many conflicting requirements. Many different strategies have been evolved during the last 10 to 15 years for cost containment and trade advantage. Some of these are outsourcing of R&D activity, forming R&D partnerships and establishing strategic alliances.<sup>6</sup>

As part of Vision 2030 and the National Transformation Program (NTP) 2020, the Saudi Government has set targets to boost local manufacturing of medical products and to develop an integrated pharmaceutical and medical device manufacturing cluster. The healthcare sector and pharmaceutical market in Saudi Arabia is the largest in the Middle East and Gulf Cooperation Council (GCC) respectively. According to Special 301 Report from U.S. Trade Representative, Saudi Arabia falls in the priority watch list with regards to providing adequate and effective IP protection and enforcement in pharmaceutical sector. Intellectual Property Rights are commonly seen as one of the most important economic assets of any corporate entity or research organization. In today's knowledge-based economy, we see how knowledge is emerging as the most fundamental economic force which promotes innovation which is a sine-quo-non to pharmaceutical industry. The pharmaceutical sector is very dependent on strong IPRs for innovation (IFPMA, 2003). It presents some unusual challenges for assessing the impact of IPRs.<sup>7</sup>

This study investigates the role that IPR's play for the dynamics of innovation in the pharmaceutical industry. The degree to which societies and, more specifically, firms benefit from the knowledge-based economy depends greatly on the extent to which they have access to or are excluded from the new knowledge.

Section one sates the introduction of Saudi Arabia's IPR followed by the literature review

highlighting the views and opinions of various authors from their study in the past and recently. Section 3 analyses the data (data retrieved from the World Bank and SAIP) followed by section 4 conclusion and policy implications.

The empirical research has been devoted to the study of the importance of the role of IPR in many countries and its effects on economic growth. In support of their argument in favour of the IPR system as a driver of economic growth, F Abbott, T Cottier and F Gurry provided an integrated perspective including history, economics and social implications and contains excerpts of articles by other authors, court cases and legal materials. They agreed that there existed strong link between intellectual property and social implications.<sup>8</sup> P David, M B Wallerstein, R A Schoen and M E Mogege, examined a concise but thoroughly comprehensive overview of the history and economics of patents, copyrights, and trade secrets. In conclusion the author argues that proposals to establish a uniform international regime of IPR protection are not practical, even though careful economic analysis would indicate that there may be considerably more points of agreement between the interests of the technologically advanced and the developing countries than has often been supposed.<sup>9</sup>

WIPO guide to IPRs arranged fields of intellectual property protection; the role of intellectual property in development and WIPO's development cooperation programme; enforcement of IPRs; international 14 treaties and conventions on intellectual property; administration and teaching of intellectual property; and technological and legal developments in intellectual property.<sup>10</sup> S Macdonald focuses on the costs rather than on the benefits of patents. The author argues that the greatest cost of all seems to be borne by society as a whole in terms of damage done to innovation, which he considers curious given that the fundamental purpose of the patent system is to encourage innovation for the benefit of society as a whole.<sup>11</sup>

M A Heller and R S Eisenburg explain why people overuse shared resources. However, the recent proliferation of IPRs in biomedical research suggests a different tragedy, an 'anti-common' in which people underuse scarce resources because too many owners can block each other. Privatization of biomedical research must be more carefully deployed to sustain both upstream research and downstream product development. Otherwise, more IPRs may lead

paradoxically to fewer useful products for improving human health.<sup>12</sup>

All the above studies suggests that rethinking the role of IPR in Saudi Arabia especially compared to other watch list countries becomes highly important to portray the efforts and efficiency of Saudi Arabia to protect its IPR not only in pharmaceutical industry but all the sectors. This paper intends to add its voice to the debate -at least in the case of Saudi Arabia- by using data and methods that will be explained in the next section to hopefully draw reliable conclusions about redefining the role of IPR and its validity to be in non-watch list countries by the US Special 301 Report.

### **Watch List and Non-Watch List Countries**

Various countries have made review and comparison of their IPR after being in watch list country, as per the US 301 Report including Saudi Arabia. When compared to many other countries in watch list and non-watch list, it was realized that Saudi Arabia has made tremendous developments in the role of IPR in various sectors including the pharmaceutical sector.

In Saudi Arabia, pharmaceutical inventions are always under intellectual property right protection. Because legal regulations for this controversial subject matter are scarce, the research about Saudi Arabian Law on intellectual property rights to pharmaceutical inventions is indeed the research about Saudi Law on intellectual property rights to inventions in general. PhRMA and its member companies are encouraged by the new leadership of SAIP which may help to make progress against the challenges that are currently being faced by innovator companies and PhRMA will continue engaging with and maintaining an open dialogue with the Saudi authorities to best improve the IP environment in the country.

Based on the guidelines of WHO for good manufacturing practices, Saudi Arabia like many other countries follows this system where risks are minimized by good and controlled production and quality standards that cannot be eliminated by just testing the final product. Also, the requirements for storage, packaging, handling and transportation of medicines and devices are fulfilled following the guidelines of The Saudi Food and Drug Authority (SFDA).

Saudi Arabia joined WIPO in 1982. It has since acceded to international treaties administered by WIPO, such as The Patent Law Treaty, The Patent

Cooperation Treaty, etc. Saudi Arabia established the Saudi Authority for Intellectual Property (SAIP) in 2017 as the sole competent IP authority for enabling the country to stimulate economic growth. SAIP along with other government authorities also creates a favorable investment climate, a more diversified and competitive national economy which is boosting IP awareness and fostering business growth. SAIP is working closely with private sector partners to implement its enforcement activities. To formalize and strengthen the participation of the business community in this work, SAIP recently established the IP Respect Council. The Council brings together private and public sector actors to discuss and exchange views on a variety of IP issues, including the challenges confronting IP owners, opportunities for collaboration, new enforcement initiatives, and policy developments requiring public comment. At its first meeting in January 2020, the Council brought together key players within the international and national pharmaceutical and biologics industries to map the challenges confronting this sector and to identify possible solutions.

SAIP is preparing the groundwork for Saudi Arabia to join various WIPO-administered international treaties. For example, Saudi Arabia recently submitted instruments of accession to the Vienna Agreement Establishing an International Classification of Figurative Elements of Marks and the Locarno Agreement Establishing an International Classification for Industrial Designs, respectively. In due course, it also expects to formally join the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure and the Strasbourg Agreement Concerning the International Patent Classification. Accession to the Madrid Protocol and the Hague Agreement, respectively, are also under review. These developments will further strengthen Saudi Arabia's national IP system, bringing it into line with international best practice.

SAIP has extended its cooperation with a range of international affiliates and signed formal cooperation agreements with the China National Intellectual Property Administration (CNIPA), the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the

United States Patent and Trademark Office (USPTO), and WIPO. These agreements are designed to facilitate the exchange of IP expertise and to support the further development of the national IP system. These crucial contributions are essential in advancing SAIP's goal to become a cutting-edge IP authority.

SAIP has also signed patent prosecution highway (PPH) agreements with the USPTO, the JPO and KIPO. Such agreements fast-track patent procedures through the sharing of patent information between participating offices, thereby reducing the workload of patent examiners and improving patent quality. In the coming months and years, SAIP will continue to invest in building IP awareness and greater respect for IP rights.

Saudi Arabia recognizes the importance of protecting IP rights to enable innovators, creators, and innovative businesses, small and large, to leverage the economic value of their intangible assets. By fostering innovation, creativity and business growth in this way, the broader population will benefit from access to a constant flow of new technologies and creative products as well as the advantages of a thriving economy. The recent evolution of Saudi Arabia's IP landscape promises to yield significant benefits and is an important step towards achieving the objectives set out in the Saudi Vision 2030.

The United Arab Emirates (UAE) is removed from the Watch List this year due to the Ministry of Health and Prevention resolving concerns with IP protection of pharmaceutical products. The UAE also made progress on longstanding IP enforcement concerns, particularly through increased efforts by Dubai Customs, publication of IP enforcement procedures by multiple enforcement authorities, publication of annual IP enforcement statistics by Federal Customs, and efforts by the Ajman Department of Economic Development to significantly reduce the availability in counterfeit goods at the Ajman China Mall, a notorious market for the past several years.

In the most significant criminal case under Taiwan's recently amended Trade Secrets Act, a Court ruled that a Taiwan semiconductor company and three former employees were guilty of stealing trade secrets from a US company to enable the development of semiconductor chips by a Chinese state-owned enterprise. The Court imposed a \$3.4 million fine on the Taiwan Company and sentenced the former employees to 5-6 years in prison. The case involved

substantial cooperation with US investigators and prosecutors.

In the area of trademarks, the traffic in pharmaceutical products and active pharmaceutical ingredients bearing counterfeit trademarks is a growing global problem, which can also endanger consumers' health and safety. The OECD-EUIPO study mapping the economic impact of trade in counterfeit and pirated goods shows that India and China are the biggest producers of counterfeit pharmaceuticals and due to the boom of e-commerce these fake products are shipped all around the world, including Europe, also in small consignments.

### Data Analysis

According to SAIP, 1,367 requests were made of patent applications between 2006 and 2021. 9,118 requests were made for trademark applications between 2013 and 2021. 352 orders for industrial model requests were made from 2011-2021. Optional copyright registration for the Department of Computer Software and Architectural Layout were also made. Also, data is retrieved from world bank from 2001 to 2021 regarding the other macro-economic variables affecting IP and economic growth of country, like patents (residents and non-residents), Manufacturing sector, Services sector, Agriculture forestry and fishing (AFF sector).

Time series data has been analyzed (Table 1) from 2001 to 2020 using the E-views program. Dependent variable is GDP and the independent variables are Agriculture, forestry and Fishing (AFF), Manufacturing (M), Patents of non-residents (NR), Patents of residents (R) and Services (S).

The model used in the study is:

$GDP = f(AFF, M, NR, R, S)$  and can be specified as follows:

$$GDP = \alpha + \alpha_1 AFF + \alpha_2 M + \alpha_3 NR + \alpha_4 R + \alpha_5 S + e_i$$

Where,

GDP = Gross Domestic Product

$\alpha$  = coefficient of the constant term

$\alpha_1, \alpha_2, \alpha_3, \alpha_4, \alpha_5$  = coefficients of the predictors; and

$e_i$  = the error term

a priori expectation is that  $\alpha_1, \alpha_2, \alpha_3, \alpha_4, \alpha_5 > 0$

### Relative Analysis of Predictors

The analysis of predictors investigates the individual contributions or relationships between economic growth variable (GDP) and other macro-

Table 1 — Descriptive Statistics

	AFF	GDP	MANUFAC...	PATENTNR	PATENTR	SERVICES
Mean	13961.95	55767.15	60119.80	818.30	367.40	20902.55
Median	14248.00	55460.50	60768.50	519.50	123.50	21461.50
Maximum	16375.00	70394.00	84941.00	2463.00	1188.00	29597.00
Minimum	11248.00	36407.00	31911.00	0.00	0.00	11397.00
Std. Dev.	1955.60	11655.50	18590.86	854.75	415.87	6443.57
Skewness	-0.08	-0.19	-0.10	0.99	0.84	-0.14
Kurtosis	1.30	1.63	1.60	2.42	2.18	1.52
Jarque-Bera	2.43	1.68	1.67	3.51	2.93	1.90
Probability	0.30	0.43	0.43	0.17	0.23	0.39
Sum	279239.00	1115343.00	1202396.00	16366.00	7348.00	418051.00
Sum Sq. Dev.	72663285.00	25811645.00	6566782.00	13881244.00	3285957.00	7888712.00
Observations	20	20	20	20	20	20

Source: World Bank data and SAIP- calculated by author

economic variables of the agriculture, forestry and fishing, Manufacturing, patents of residents and non-residents, and services. It also tests for the direction and magnitude of such relationships.

The results in Table 1 show that all five independent variables are positively related to GDP. This is in line with a priori expectation that  $\alpha_1, \alpha_2, \alpha_3, \alpha_4, \alpha_5 > 0$ . Thus, the values of the coefficients of the independent variables are 13961, 60119, 818, 367 and 20902 respectively. This indicate that for every, one unit change in any of the independent variables, GDP is predicted to change by 13961, 60119, 818, 367 and 20902 respectively in the same direction.

But all three independent variables were individually statistically insignificant in their relationship with Gross Domestic Product 5% level, but quite significant at the 10% level. The implications here is that each independent variable taken as an individual does not significantly contribute to economic growth but taken as a unit, they are statistically significant as shown by the global statistics.

Tables 2 & 3 shows that t-statistic is computed as the ratio of an estimated coefficient to its standard error and is used to test the hypothesis that a coefficient is equal to zero. To interpret the t-statistic, we examined the probability of observing the t-statistic given that the coefficient is equal to zero. It can be seen that the dependent variable is GDP (Gross domestic product). Method of analysis used is ordinary Least Square. The sample was collected for the period covering 2001 to 2020 and the number of observations (sample size) is 20 (years).

Relative statistics relates to the specific variables used in the study as: From the output the variable

being AFF (Agriculture, Forestry, and fishing) as well as cultivation of crops and livestock production. Value added is the net output of a sector after adding up all outputs and subtracting intermediate inputs. It is calculated without making deductions for depreciation of fabricated assets or depletion and degradation of natural resources. The origin of value added is determined by the International Standard Industrial Classification (ISIC), revision. Data are in constant local currency.

From the output, the coefficient of AFF is 1.4476780. This value means that there is a positive relationship between AFF and GDP with the implication that every unit increase in AFF is predicted to be accompanied by 1.4476780 units increase in GDP. The standard error of the regression coefficient is 1.063289. This value identifies limit of error is expected to be inherent in the result. From the result, the expected error in the result is plus or minus 6.32%.

The next is the t-statistic which gives a reading of 1.360. Here the output t-statistic is greater than the critical t-statistic, therefore, the null hypothesis is rejected, and we conclude that AFF significantly affects GDP. The Prob of the above t-statistic indicate that indeed AFF is statistically significant @ 1% confidence level.

For a basic multiple regression analysis, R-Square (coefficient of determination) gives the value of 0.992495. This value implies that AFF, Manufacturing, services, patents both residents and non-residents can be relied on to explain 99.24% of the variations in GDP. The Adjusted R-Square result also indicates that the level of error is negligible (approximately 0.42%).

Table 2 — Covariance Analysis

	AFF	GDP	MANUFAC...	PATENTNR	PATENTR	SERVICES
Mean	13961.95	55767.15	60119.80	818.30	367.40	20902.55
Median	14248.00	55460.50	60768.50	519.50	123.50	21461.50
Maximum	16375.00	70394.00	84941.00	2463.00	1188.00	29597.00
Minimum	11248.00	36407.00	31911.00	0.00	0.00	11397.00
Std. Dev.	1955.60	11655.50	18590.86	854.75	415.87	6443.57
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Kurtosis	1.30	1.63	1.60	2.42	2.18	1.52
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Observations	20	20	20	20	20	20

Source: World Bank data and SAIP- calculated by author

Table 3 — Least Square Method

Variable	Coefficient	Std. Error	t-Statistic	Prob.
C	6377.036	8699.004	0.733077	0.4756
AFF	1.44678	1.063289	1.360665	0.1951
MANUFACTURING	0.629463	0.148508	4.238584	0.0008
SERVICES	-0.376859	0.514697	-0.732197	0.4761
PATENTNR	-0.927975	0.838844	-1.106254	0.2873
PATENTR	-0.044199	2.264689	-0.019517	0.9847
R-squared	0.992495	Mean dependent var		55767.15
Adjusted R-squared	0.989815	S.D. dependent var		11655.50
S.E. of regression	1176.29	Akaike info criterion		17.22144
Sum squared resid	19371201	Schwarz criterion		17.52016
Log likelihood	-166.2144	Hannan-Quinn criter.		17.27976
F-statistic	370.2931	Durbin-Watson stat		1.427196
Prob(F-statistic)	0			

Source: World Bank data and SAIP- calculated by author

The Durbin-Watson stat which is a diagnostic statistic which tests for the presence of auto-serial correlation in the data. As a rule of thumb, Durbin-Watson statistic runs from 0, 1, 2, 3 and 4. A value close as possible to the central value of 2 indicates the absence of auto-serial correlation while any value far to the left or right indicate the presence of negative or positive auto-serial correlation with the implication that the results may not be entirely reliable. Here, the result indicates the presence of negative auto serial correlation.

## Conclusion

It is obvious that management of IP and IPR is a multidimensional task and calls for many different actions and strategies which need to be aligned with national laws and international treaties and practices.

With this paper it was attempted to redefine and rethink the role of pharmaceutical industry to work on

different domains such as science, engineering, medicines, law, finance, marketing, and economics. Pharmaceutical industry currently has an evolving IP strategy. Since there exists the increased possibility that some IPR are invalid, antitrust law, therefore, needs to step in to ensure that invalid rights are not being unlawfully asserted to establish and maintain illegitimate, albeit limited, monopolies within the pharmaceutical industry.

With the vision of SAIP to be an integrated intellectual property authority with a global perspective and a leading intellectual property moderator in the MENA region, it has become possible to achieve the national goals for IP with the strategic goals of SAIP of Improving Intellectual Property strategies, regulations, and legislation. Raising the customer's level of focus, attractiveness and quality of products and services. Contributing to the empowerment and exploitation of intellectual

property rights. Thus with this paper we highlight the fact that IP and its associated rights are seriously influenced by the market needs, market response, cost involved in translating IP into commercial venture and so on.

In other words, trade and commerce considerations are important in the management of IPR. Different forms of IPR demand different treatment, handling, planning, and strategies and engagement of persons. Each industry should evolve its own IP policies, management style, strategies, etc. depending on its area of specialty.

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