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The impact of protection of the intellectual property rights on the pharmaceutical market in India

This article is the second part in a series of texts entitled:
"**The current problems of drug management in countries of the Indian subcontinent"**

Key words: Intellectual Property Rights, IPR, TRIPS, India, pharmaceutical market, access to drugs

The burden of diseases in India – in the light of health care financing

India is struggling not only against communicable diseases but also carries a large burden of non-communicable diseases. India is one of the 10 countries hosting 75% of the children who had not received vaccines for vaccine preventable diseases, like diphtheria, pertusis and tetanus. The diseases caused by Haemophilus, Pneumococcus and Rotaviruses, which are causing 2.1 million deaths in all age groups worldwide, have not even nudged the Indian government to provide access to the appropriate vaccines [1]. For the pharmaceutical industry, R&D (research & development) on vaccines is not that profitable as the purchases are made by the government and moreover, the use is only for one time. There is a lack of vaccine coverage in the developing world and there is a growing need for developing new and better vaccines.

The epidemiologic status of India with regard to the infectious diseases is no different. The so called diseases of the poor, namely malaria, tuberculosis, leprosy, leishmaniasis, dengue and lately HIV and AIDS have added a severe toll on the country's health status. Malaria is killing around 1 million people worldwide [2]. It is affecting the most vulnerable population and has severe impact on the overall economic growth of many nations [3]. Most of the drugs used in malaria are reportedly becoming less effective due to the drug resistance. It has been ages since any major breakthroughs have been made in the treatment of this disease.

India has got the largest burden of tuberculosis (TB) in the world. TB is killing an individual every two minutes. In recent times the situation has only worsened with the co-occurrence of TB and HIV. To add to this insult, the incidence of drug- and multi-drug-resistant TB is on the rise. The prime reason is irregular or only partial treatment. The diagnosis, treatment and even the vaccine are dependent on old and imperfect technologies [4].

Over the last few years a growing number of people have been infected with HIV. Poor countries have the highest patient load and India carries the third largest burden of HIV cases. The number of people dying from AIDS is on a constant rise. Irrespective of the current scenario there is still limited or no access to antiretroviral therapy in many nations [5]. In the recent times many of the toughest IPR (Intellectual Property Rights) legal battles have been fought over access to the anti-retroviral therapies (ARTs) for people living with HIV and AIDS. Millions of these people in the countries bearing the maximum burden of the disease have been treated with generic drugs manufactured just in India. The Indian pharmaceutical manufacturers like CIPLA have been offering ART drugs at as low price as $ 350 per year in comparison with that of $ 10,000 per year as priced by the Western drug industry. Competition caused by the Indian generic manufacturers managed to bring down the prices by around 98% but since their accession to the TRIPS accord (see below), the Indian manufacturers are forced to withhold their exports, resulting in millions of people waiting or perishing in need for the therapy [6].

The situation of other neglected diseases affecting the poor people is identical. These diseases are peculiarly having a large prevalence in the low-income developing world, a lower burden in the developed nations, and a low level of funding in comparison to the disease burden. As with most of the neglected diseases, the apparent lack of a profitable consumer market for appropriate drugs and the fact that the neglected diseases concern the developing countries, are used to explain the relatively low level of R&D investment of the pharmaceutical giants. This under-funding of research in the area of the neglected

diseases of the poor is known as the "10/90 gap" which refers to the point that lesser than 10% of the global R&D expenditure is devoted to the diseases and conditions associated with 90% of the world population [7].

Sadly, it is the low and middle income countries that are bearing the double brunt of communicable and non-communicable diseases. India has already become the diabetes capital of the world and at the same time India loses around 2.5 million people to malaria, respiratory infections, diarrhea and other infections, annually [8].

The lack of the access to essential medicines is the worst in India and Africa. Ironically, 15% of the entire world's population, most of them living in the developed countries, consumes 91% of the drugs produced [9]. WHO estimates that the prompt diagnosis and the appropriate management with the use of medicines can save around 4 million lives annually in South-East Asia and Africa [10]. The data on the global spending on drugs shows that most of the drug sale is done in the developed world with the USA leading in statistics, with share of almost half of the total sales. The USA, Europe and Japan together account for almost 86%. The global share of developing countries, like India and Africa together is just 2.3% [11].

The UN Millennium Project identified the six most important hurdles in accessing health care; four of them were on already existing medicines and two were related to the development of the cost-effective new medicines and vaccines. The report emphasizes that the developed nations failed to keep their promises in providing adequate monetary and technical support to the developing world. It has also pointed out that the TRIPS agreement may cause an additional blockade in accessing new therapies and vaccines at affordable prices. It would be having a major impact on countries like India, as this country would no longer be able to produce or supply the vital generic drugs, not only to their local markets but also to their African counterparts. Moreover, the existing incentives in the developing world are insufficient to foster research and inventions for diseases specific to these countries. However, the "Doha Declaration on TRIPS and Public Health" restated and re-affirmed that the public health matters override the IPR matters and that the member States can take all necessary measures to ensure the same. In fact, this is highly questionable.

As in many developing countries, the private expenditure on health in India is higher than the government contribution. Another important feature is that only 4.8% of the GDP is the overall contribution towards health. The trend in India is discouraging, as in addition to the low total expenditure on health as a percent of the GDP, the central government spending is also on decline. Therefore it is clear that the majority of health care funding in India comes in fact from the out-of-pocket (OOP) expenses, making the health care system in India one of the world's most privatized. It is amazing to find that the private OOP expenses on medicines take the largest share of households expenditures in many developing countries. They may go from 50% to as high as 90% of the sales of medicines [12]. Drugs form the majority of the OOP expenses in health care expenditures of India. The average OOP expenses are estimated to be in the range of 80.9% of the total private health expenditures. The total public health expenditure is less than 10% on drugs.

In India 26% of the population live below the poverty line. The poor lack the access to essential medicines for many reasons, all of which must be addressed in a comprehensive manner. The most important reason, by far, is the poverty itself, which means that neither the poor nor their governments can afford to purchase the essential medicines or ensure their proper use in well – run health care systems. It is important to say that the Indian health care system uses very little governmental funding and it is predominantly privately owned and based on the OOP financing.

The data from **Tables I** and **II** (below) allow to make some comparisons and reflect the characteristics of the health care financing in India and on the position of the Indian subcontinent's pharmaceutical market.

Region	2004	2005	Global share of sales 2005 (%)
North America	249.0	268.8	44.4
Europe	169.2	180.4	29.8
Japan	66.1	69.3	11.4
Oceana	7.1	7.7	1.3
CIS	4.2	5.0	0.8
South-east Asia	25.3	28.8	4.6
Latin America	24.4	26.6	4.4
Indian sub-continent	6.6	7.2	1.2
Africa	6.3	6.7	1.1
Middle-east	4.7	4.9	0.8
Total world Market	562.9	605.4	100.0

Table I. *Global pharmaceutical market by region, USD billion, ex manufacturer prices (Bloom B.R. et al., 2006).*

Country	HDI rank	Health expenditure		
		Public (%) of GDP	Private (%) of GDP	Per capita (PPP USS)
United States	8	6.8	8.4	5,711
Korea, Rep. of	26	2.8	2.8	1,074
Brazil	69	3.4	4.2	597
Thailand	74	2.0	1.3	260
China	81	2.0	3.6	278
India	126	1.2	3.6	82

Table II. *Expenditure on health of some selected countries in 2003 (WHO report, 2006).*

The international dimension of the intellectual property rights

The intellectual property rights (IPR) are the rights granted to a person or an industry for their innovation or creation. This allows the innovators to prevent others from unsanctioned use of their products, in terms of manufacturing, selling, distributing, procuring and exporting; usually for a timeframe of 20 years. To obtain these rights the innovator should reveal the information on which the invention is based. These rights provide an opportunity to the manufacturer, to produce the drugs without any competition and at prices determined on their own terms. This will enable the innovators to recuperate costs invested into the research and development of their products and to gain the net profits.

In 1947, 23 nations reached the General Agreement on Trade and Tariffs (GATT) to promote and regulate the international trade [13]. In 1995, the World Trade Organization (WTO) was created to succeed the GATT. Currently the WTO has 141 member countries, including India. According to the WTO treaty all members must introduce patent regime for product and/or process in accordance with the trade-related aspects of the intellectual property rights (TRIPS). To enforce this, the uniform standards were set by all member nations so as to strengthen and harmonize the protection of the IPR. The agreement was relevant also for the production of pharmaceuticals. The agreement gave different deadlines to different countries depending on their stage of development. India had to comply with the regulations by 1st January 2005 [14], which meant that one decade was given to India to adopt laws for protecting the IPR. Several factors (the continuous advancement in science; the new breakthroughs in bio-technology; the growing participation of the private sector in the cost-intensive research and development activities performed in the knowledge-based pharmaceutical sector; the relative strength demonstrated by the developing nations in adopting the results of scientific innovations into their local environments) have prompted the industrialized nations to seek stronger protection for innovations.

The pharmaceutical sector employs technological capabilities that are rooted in innovative drug discovery and development activities (product development), technological capabilities related to discovering different processes of producing drugs (process development), and finally, technology related to producing and packaging formulations (manufacturing). Certain limitations render it hard for developing countries to build these capacities in the pharmaceutical sector. The developing countries accounted for less than 2% of the total number of patents during the 1997–1996 period [15]. At the macro level, there is a gap between demand for health research and ongoing activities in the sector, a lack of scientific culture amongst scientists and researchers (including emphasis on collaboration), weak public support and bureaucratic rigidity. At the facility level, there are problems related to access to information and technological inputs that are important for health research, inadequate human capital formation, institutional instability and weak infrastructure. And at the terminal level, the issues of intellectual isolation of researchers and lack of incentives for collaboration, low salaries, restriction of career growth due to bureaucratic bottlenecks, and lack of the on-the-job training possibilities, make it hard to create the efficient innovative environment.

The entire discussion about the impact of the TRIPS agreement on the health system revolves around two main opposing arguments. The TRIPS supporters claim that enforcing the patent law will spur innovation and would provide incentives for new path-breaking research. On the other hand, people who are lobbying against TRIPS state that it would not only increase the divide between the rich and the poor but it would also decrease the access to medicines [16]. Unfortunately, there are still no documents showing a positive impact of TRIPS on spurring the innovative research process although the member countries from the third world are also bearing the cost of enforcing the TRIPS agreement [17].

The past and the present of the Indian pharmaceutical market

Until 2005 India had no exclusive patent protection. The Indian Patents Act of 1970 aimed to make the country self-sufficient in terms of medicines and it gave protection related only to process patents. It suited the Indian pharmaceutical industry, which exploited it by specializing in modifications of the manufacturing processes, what popularly came to be known as the "reverse engineering" [18]. This served the national interest as well, since India could manufacture cheaper generic alternatives to many medicines, which were patented in other countries. Due to this, the dramatic growth of the Indian pharmaceutical industry has been observed in the last 30 years. The market structure started to change. The share of multinational subsidiaries declined from 80 to 90% in 1970, to roughly 30% in 2000. Indian firms started becoming the major exporters in the global market. Indian pharmaceutical industry exported medicines at affordable prices to 200 countries across the globe, which brought in the foreign exchange to the country. Due to the high technical knowledge, entrepreneurial skills, state of the art facilities, low clinical studies costs, low capital costs and highly skilled labour force, the Indian pharmaceutical industry has witnessed a tremendous growth in last decades and it emerged as one of the leading industries in the world. India currently holds the 4th position in terms of volume and the 13th one in terms of production in the world [19] and it secures the access to essential medicines in the developing world, at a relatively low cost [20]. In the pharmaceutical sector India is often cited as an example of an "innovative developing country" with significant capacity to carry out health care innovation. Indian generic firms are an important source of medicinal supply both domestically and internationally. They presently produce 22% of all generic drugs worldwide. The total market value is close to 8 billion dollars and bulk drugs form almost 40%

of the domestic pharmaceutical industry capacity. The Mashelkar Committee [27] identifies 5,877 (licensed) drug manufacturing units and 10,400 units involved in manufacturing of other substances as ancillary units. The annual growth rate has been quite high with bulk drugs registering the growth of 12.38% and the growth of 11.05% in formulations, contributing to a total production increase of 11.17%.

Although the growth of the Indian pharmaceutical market is phenomenal, it is uneven. Ten of the top 25 drugs sold in India are hazardous, irrational and non-essential [21]. Market for drugs is also highly concentrated with the substantial market share controlled by an average of four to eight companies only. The competition is therefore somewhat restricted.

The 1st of January 2005 was a historic deadline for the Indian pharmaceutical industry. Before that date the "reverse engineering" was a tool in hand of this industry (based on the patent laws of India of 1970) by which the industry could make any patented molecule. The drug companies soon became experts in the process of reverse engineering and they manufactured in India the less expensive copies of the world's best-selling and patent-protected drugs. The Indian industry grew and prospered in a highly regulated environment with government price controls on many formulations and bulk drugs. Nowadays, under the new patent law of 2005, the drug companies are no longer allowed to manufacture and market reverse-engineered products originated by the foreign drug manufacturers.

In December 2004 the Government of India promulgated the ordinance incorporating the product patent regime to meet the deadline set by the WTO for protection of the IPR. The Patent Bill was passed by the Indian parliament on 22nd of March 2005 and The President of India gave assent to it on 5th of April 2005. Now it is known as The Patent (Third Amendment) Act 2005 and it extends patent protection offering both product and process patents. The earlier patent law of 1970 allowed manufacturing generic drugs, offering only the process patents. It helped India to emerge as the major producer and exporter of pharmaceuticals for the whole world. Now the pharmaceutical companies have to make provisions for high inputs into the research area in order to develop the new products. Under the new Act the patent holder of a product will continue to retain the IPR and will have to be compensated if others manufacture its product. Any manufacturer of generics can apply to copy a patented drug after it has been marketed for three years – after paying a reasonable royalty to the patent holder. This has brought a new challenge to the Indian industry, as it would no longer be able to manufacture generics without ensuring royalties to their originators.

Since the Indian industries are important suppliers of finished products and low-priced active ingredients, both domestically and to many developing and developed countries, the common fear has been that the new patent laws may destroy these industries, leading to the increases of drug prices. On the other hand, as a result of TRIPS compliance, the Indian pharmaceutical companies have increased their exports of generic drugs to the more regulated markets of the USA and Europe. This has also prompted the Indian companies to enter into agreements and mergers for R&D purposes and into other alliances. From this point of view the TRIPS agreement has indeed done a lot of good to the business community and it helped orient the business towards the well developed markets, with an eye on R&D and innovation. The substantially growing list of the companies clearing the American FDA (Food and Drug Administration) approval process [22] enhances their chances for contract manufacturing of drugs and for easing the norms for exporting drugs to the highly regulated markets of the Western world. This would increase the business revenues, which are (in principle) reinvested into the development of new molecules and the product development. Also, the TRIPS agreement paves the way for exporting drugs to the lower-income countries, which cannot afford to buy the compulsory licenses under the new regime; facilitating therefore the global distribution of drugs.

The TRIPS accord mandates data exclusivity of drugs, discouraging this way the low-cost generic producers entry into the market. However, the national rights of compulsory licensing would counteract in some of such situations, especially with respect to drugs used in the treatment of HIV infection. Also, it is important to mention that the majority of drugs on the WHO's list of essential drugs (close to 95% of them) are off-patent drugs [23]. Therefore, the implementation of new patent regimes doesn't affect prices of the essential drugs.

The control of drug prices is done by the national pharmaceutical pricing authority under the price control legislations. However, the new drug price may not be exactly determined because of the lack of benchmark price. The multinational companies can manipulate import costs, ultimately leading to the cost based on the bargaining power of the companies and the government. The lack of the developed insurance system and the low domestic purchasing power will together force the pharmaceutical companies to keep market prices as low.

The summary impact of the TRIPS regulations on the Indian pharmaceutical industry

The Indian pharmaceutical industry has evolved over three phases. The first one was the period prior to 1970, when the industry was dominated by a small set of foreign-owned and foreign-controlled firms. The second phase, spanning from the second half of the 1970s to the early 1990s, was a period during which the industry experienced the structural transformation through the growth of the Indian generic industry. Much of the credit for this development should be taken by the Patents Act of 1970. In the third phase, i.e. since the early 1990s, the pharmaceutical industry has seen the rapid consolidation of generic producers on their positions. The decade of the 1990s witnessed the strongest performance of the Indian pharmaceutical industry on several fronts [24]. Over 20,000 registered pharmaceutical manufacturers

exist in the country. The domestic pharmaceuticals industry output exceeded INR (Indian Rupee) 260 billion in the financial year 2002, which accounts for merely 1.3% of the global pharmaceutical sector. Out of this, the bulk drugs account for INR 54 billion (21%) and the formulations for the remaining INR 210 billion (79%). In financial year 2001 imports were INR 20 billion, while exports were INR 87 billion [25]. The Indian pharmaceutical sector has come a long way, being almost non-existing during 1970s, to the position of a prominent provider of health care products, meeting almost 95% of country's pharmaceutical needs. The domestic pharmaceutical output has increased at a compound growth rate (CAGR) of 13,7% per annum. Currently the Indian pharmaceutical industry is valued at approximately $ 8.0 billion. As previously stated, globally the Indian industry ranks 4th in terms of volume and 13th in terms of value. The exports constitute almost 40% of the total production of pharmaceuticals in India. India's pharmaceutical exports are to the tune of $3.5 billion currently, of which formulations contribute to nearly 55% and the remaining 45% comes from bulk drugs [26].

The following aspects should be highlighted in a SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis of the Indian pharmaceutical industry impacted by TRIPS in the recent years:

Strengths

- Cost competitiveness of the Indian pharmaceutical industry.
- Well developed industry with strong manufacturing base.
- Access to pool of highly trained scientists, both in India and abroad.
- Strong marketing and distribution network.
- Rich biodiversity.
- Competencies in chemistry and process development.
- Huge advantage of possessing the knowledge of the traditional medicine which is accepted by many in India and across the world.

Weaknesses

- Low investments in innovative R&D and lack of resources to compete with MNCs (Multi-National Companies) for new drug discovery research and to commercialize molecules on a worldwide basis.
- Lack of strong linkages between industry and academia.
- Low medical expenditure and healthcare spend in the country.
- Production of spurious and low quality drugs tarnishes the image of industry at home and abroad. The drug control system in India is still poor. The drugs manufactured can be reexported after repacking or black marketed in other low-income markets and thus resulting in the decrease of quality of drugs, more often leading to the problem of accessing proper drugs in spite of availability. India forms the major market for the counterfeit drugs exported to the Third World countries. The drug monitoring systems have to be strengthened to reduce the problem of the counterfeit drugs.

Opportunities

- Significant export potential.
- Licensing deals with MNCs for New Chemical Entities (NCEs) and Novel Drug Delivery System (NDDS).
- Marketing alliances to sell MNC products in domestic market.
- Contract manufacturing arrangements with MNCs.
- Potential for developing India as a centre for international clinical trials and a niche player in global pharmaceutical R&D.
- Supply of generic drugs to developed markets.
- With the accession to the TRIPS agreement, the Indian government has opened the door for accessing the western markets and many companies are already exporting drugs to highly regulated market. This improves quality as more compliance is needed to adhere to the FDA standards and maintain good manufacturing practices (GMP-s). Also, this has made possible for simultaneous availability of the drug in multiple markets, cutting down the lag periods in the availability, in the low income markets.
- Bigger players on the international pharmaceutical market have always focused on the R&D activity and are spending on that a significant part of their turnover. R&D cost is much lower in India, but only a fraction of compounds synthesized is launched commercially. An option is for companies to get into research exclusively and enter into contracts with larger players which the TRIPS agreement is giving a major boost. With increase of sales and profits, some of the money is used to invest in the research and development of new methods and drugs.
- More research and facilitation of IPR-s would be highly favorable to Indian manufacturers and market to expand the segment of traditional pharmaceuticals as a rival to the modern medical drugs.

Threats

- Product patent regime poses serious challenge to domestic industry unless it invests in R&D.
- R&D efforts of Indian pharmaceutical companies can be hampered by the lack of enabling regulatory requirement.
- Drug Price Control Order puts unrealistic ceilings on product prices and profitability and prevents pharmaceutical companies from generating investible surplus.
- Lowering of the tariff protection.
- The new excise duty regime threatens the existence of many small scale pharmaceutical units, especially in the states of Andhra Pradesh and Maharashtra, that were involved in contract manufacturing for

the larger, established players. These companies are now shifting their manufacturing from these states to other ones that enjoy tax holidays.

- Political will and direction is needed as well as appropriate health policy. Government should take the advantage of global funding mechanisms to encourage contributions from high income countries, partially financing the medical programs which help in the reduction of costs borne by the poor people. Steps have to be taken to utilize the capacity of cheap drugs available in the market and encouraging public private partnerships and using effectively TRIPS flexibilities are some of the key steps to be looked into. Formulating alternative intellectual property strategies and looking into possibilities of amendments should be looked into.

Conclusions

India has a matured pharmaceutical industry and the challenges are formidable after the accession to the TRIPS agreement. Besides engaging in a constant process of reviewing the newly amended Patents Act, India would have to take complementary measures to ensure that the pharmaceutical firms are not able to secure benefits that run contrary to the fundamental objective of providing access to medicines at affordable prices. A legal regime for preventing misuse of patent monopoly would be an essential component of such measures. The structure of the patent regime and the nature of its impact on prices of pharmaceutical products may require initiatives that are beyond the scope of the patent legislation. The controversial issue of statutory control over the prices of drugs becomes relevant in this context. But above all, the developing countries would need to ensure that their TRIPS-consistent patent laws provide the balance of rights and obligations.

The TRIPS agreement has positively influenced the Indian pharmaceutical industry in terms of orienting it towards well developed markets. But on the other hand, the Indian drug manufacturers have been major suppliers of medicines both for India and for many low-income countries of Africa. Generics have been the mainstay of India's production and they have been responsible for cutting down prices of many drugs. The chances of innovation related to the novel drugs have been slim in India and they would remain so until the developed world keeps its promise to invest into neglected diseases. Around the world, people are in need of medicines and most of them live in the low-income countries. If the curbs on affordable generic drugs keep on going, then the existing lack of access would only deteriorate further.

The issue of the IPR is particularly relevant in case of HIV and AIDS. HIV is killing millions of people in countries already ravaged by wars, famine and poverty, countries which even lack the basic facilities to provide treatment to their infected citizens. The excessive IPR provisions in India could have also the negative impact on health care systems. It is argued that these provisions were not followed by any developed country during its economic development and they will form a heavy burden on the weak, developing economies. Despite the achievements in overall progress and economic reforms of the last decade, India could loose a "golden opportunity" to create and advance India's health care system in order to provide health care services and drugs for people who need them so desperately.

Persisting with tough patent protection to drugs, as stated in TRIPS, could end the India's public health care system's capacity to provide all the necessary and life-saving drugs to its population and it would prevent other developing countries (especially in Africa) from ever achieving health care coverage and affordable drugs provision. It is often argued that the IPR provisions of the TRPIS benefit only a handful of large pharmaceutical corporations, at the cost of the health of millions of citizens. The sensitive IPR issues imposed by the government of the people, by the people and for the people, are being run by a handful of corporations that are desperate to protect their profits. Such aggressive tactics, at the expense of social welfare in a region that desperately needs it, do not serve the developed nations interests in the long run as they diminish their moral standing in the world. Finally, the world has to find a striking chord which would be able to provide the essential medicines for the poor and at the same time to provide incentives for innovation. Until this is achieved, millions of people in developing nations will die without life-saving drugs and millions of people will be getting over-medicated in the developed world.

Streszczenie:

Wpływ ochrony praw własności intelektualnej na rynek leków w Indiach

Słowa kluczowe: prawa własności intelektualnej, IPR, TRIPS, rynek leków, dostępność leków

Artykuł opisuje wpływ, jaki na system opieki zdrowotnej w Indiach wywiera realizacja ochrony praw własności intelektualnej w obszarze leków. Wpływ porozumień TRIPS na innowację farmaceutyczną, dotąd uważany głównie za pozytywny, jest obecnie poddawany analizom i dyskutowany. Porozumienia TRIPS w dużej mierze pomogły rozwinąć przedsiębiorczość w Indiach i wpłynęły na zorientowanie jej na rynki krajów rozwiniętych. Przemysł farmaceutyczny w Indiach przeszedł ewolucję trójfazową, w latach 70. ubiegłego wieku rozwijając się praktycznie od podstaw. Obecnie indyjska produkcja farmaceutyczna zaspokaja prawie 95% potrzeb lekowych całego kraju. Na podstawie schematu SWOT w artykule przeprowadzono analizę wpływu TRIPS na indyjski przemysł farmaceutyczny.

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