Intellectual Property, the Hope Bringer in Medical Field

Jiaxu He

Professor: Paul Bohman

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Introduction

In 2018, a Chinese movie named Dying to Survive gained all the attention and became the top searching target in the year. Not only because it got a box office of 453 million dollars, but also it was the very first movie in China talks about the topics include “Government Medical Policies” and “Expensive Drugs”. In the movie, a Chronic Granulocytic Leukemia patient found an aphrodisiac peddler, Cheng Yong, to help him to smuggle some cheap cancer medicine from India. Cheng Yong agreed to help him because he also needed money for his father’s brain surgery. After that, Cheng Yong could not stop smuggling the cancer drugs since he noticed the profit in the difference between the cancer drug prices in China and India. He quit for a while after several times of police investigations. But he restarted the smuggling after the first patient, who persuaded him to smuggle, dead without cheap drugs. The only difference is that Cheng Yong smuggled for non-profit this time. He ended up in prison in the movie. However, this film is based on a real-life story, a man named Lu Yong is a Chronic Granulocytic Leukemia patient. He smuggled cheap cancer drugs from India for himself and other patients he knows. As more and more patients found him for cheap drugs, he could not refuse those poor patients but only increase the amount he smuggled. He got arrested in the end, but the procuratorate requested the court to withdraw the lawsuit after reconsidering the case. More than hundreds of patients wrote letters to the court to ask the judiciary to exempt him from criminal service. In the end, he was acquitted.

The film kind of designed and built a heroic impression for Cheng Yong or Lu Yong. They saved more than thousands of lives by smuggling cheap cancer drugs even though their behaviors against the law. A lot of patients that Cheng Yong or Lu Yong helped supported them when they got sued by procuratorate. However, as the movie be discussed more and more, more

different opinions occurred in the reviews. The intellectual property has been brought up, and people started to pay attention to the intellectual property situation in the medical area. The intellectual property policies in China have been discussed repeatedly from different perspectives. Although a lot of people still agree with the behaviors of Cheng Yong and Lu Yong from an ethical perspective because a lot of low-income patients' lives had been saved, they have not considered the problem fully enough. The laws of intellectual property exist include a lot of reasons. The extremely expensive cancer drugs that Chronic Granulocytic Leukemia patients cannot afford were protected by the laws of intellectual property to help the inventors to recover the cost they spent on the drugs development instead of just making them rich. The intellectual property laws also encourage more and more inventors to devote to drug developments in the medical area, and it exempts those inventors from concerns about too much investment in researching and development of drug creation processes. Although the medical treatments under the protection of intellectual property cannot fit all patients' needs, especially for low-income patients, protecting the intellectual property rights of medical treatments inventors still play an important role in the improvement of medical technologies, and it guarantees key medical benefits for the future generations.

The History of Intellectual Property

The original theory of intellectual property was found in Europe in 500 BC. In ancient Italian capital Sybaris, a Greek colony, known for its extravagant life, a cooking method was granted a one-year exclusive right. Later, after a long period of development, in the twelfth century, countries with earlier nascent capitalism represented by the United Kingdom began a campaign to introduce technology and establish new industries. Between 1324 and 1377, during the reign of Edward II to III in the United Kingdom, many foreign weavers and miners were

granted the exclusive right to use the technology, the monopoly, to encourage them to start a business in the UK. To make Britain develop from a grazing country to an industrialized country. During this period, intellectual properties were mainly expressed in monopoly to encourage the establishment of new industries, but power was often abused. In the fifteenth century to the nineteenth century, the capitalist countries represented by the United Kingdom have made useful explorations in the establishment of intellectual property laws and the implementation of intellectual property systems, which have set a good example for the countries of the world and has promoted the rapid spread of the intellectual property system worldwide. On March 19, 1474, the Republic of Venice enacted the world's first intellectual property law, officially known as the Inventor Bylaws, from 1475 to the 16th century, in Venice, many important industrial inventions, such as lifting water Machines, rice mills, drain, canal excavators, etc. are awarded a 10-year license. In 1449, the birthplace of the bourgeois industrial revolution, the United Kingdom produced the earliest invention of intellectual property. During the reign of Queen Elizabeth, there was a small climax in intellectual property licensing activities. Between 1561 and 1590, the King approved 50 intellectual properties on the manufacturing methods of knives, soap, paper, saltpeter, and leather. Regrettably, the intellectual property system at this time has a poor prestige, the name of the intellectual property is not in conformity, and the abuse of power by the intellectual property owners is widespread. From the 17th century, the UK began the reform of the intellectual property system, first abolishing all previous intellectual properties. And all the intellectual properties were assigned intellectual property numbers since 1617. 1624 is an important year in the history of intellectual property, and the British Monopoly Law began to implement. The Monopoly Law declares that all monopolies, licenses, and authorizations are invalid. In the future, only the first true inventor of a newly manufactured product will be granted

an intellectual property certificate and privilege to exclusively implement or manufacture the product in the country for fourteen years or less. Others may not use it when granting intellectual property certificates and privileges. The Monopoly Law is recognized as the originator of modern intellectual property law, which clearly defines some basic areas of intellectual property law that still have a significant impact on today's intellectual property law. Since then, other countries in Europe and the United States have followed suit, and medical intellectual property starts to gain attention during this time.

Approaching Changes for Medical Intellectual Property

Due to the terrible infectious diseases and high death rates, every new effective medical treatment invented in the nineteenth-century and twentieth-century meant power and wealth. For the large pharmaceutical companies in Europe and the US, they urged to pursue the protection from the laws for their medical treatments because of the huge profits inside. Then, they began lobbying and even bribing the governments on the legislation of such medical intellectual property laws. As more and more pharmaceutical and chemical companies started to learn using the rights of medical intellectual property as their strategies in business negotiation, they paid more attention and contributed to the evolving of medical intellectual property rights. And under such circumstances, the World Trade Organization passed an agreement called Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the 1980s. US, European and Japanese pharmaceutical and chemical companies led the negotiations to produce the agreement on intellectual property rights among all WTO member countries from 1989 to 1994 when the agreement was finalized. The key provisions of TRIPS include patent protection, protection of data submitted for the registration of pharmaceuticals, and transition period. Patent protection in TRIPS requires all the members in WTO to provide a minimum term of 20 years of protection

for any patent invention of medicine or medical treatment process. Protection of data submitted for the registration of pharmaceuticals asks members in WTO to protect the testing data that submitted to authorities for marketing approval. And the transition period helps developing countries to gain more time before they have to meet all TRIPS requirements on the pharmaceutical products patent protection.

The TRIPS created an international obligation and set the intellectual property rights under the same common international rules in the trading system between WTO members for the first time. In this agreement, the intellectual property has been generally accepted into Patents, Copyrights, Trade Secrets, and Trademarks. As essential products for the public, medicines or medical treatments did not have rights or laws to be protected in more than fifty countries before the agreement. And most WTO members reformed their intellectual property laws in the medical area to grant the patents on medicines or medical treatments after the TRIPS. However, for the countries that lack intellectual property experts, they agreed to the negotiations and voted yes to the TRIPS in exchange for other benefits for them include more export business in other fields. Since medicine patents have been officially recognized among the countries, the TRIPS meant a great impact to the cost of the patented medicine and the situation of generics in the countries that had no previous medicine patent protections. However, the approval of TRIPS in WTO also encouraged more and more pharmaceutical and chemical companies to establish and put more effort into researching and developing of new medicine and medical treatments. Moreover, more new medical technologies, medical treatments have been invented since then. And a lot of diseases were thought incurable have been conquered by humans in the last few decades.

New Drugs Production Process

Although the improvement in medical technologies is impressive in the last century, the processes for the human to conquer those diseases were not as easy as many people thought they could. As part of the result of TRIPS, newly invented drugs have an extremely high price that was allowed and protected around the world. And those new drugs are barely affordable for low-income patients, whose lives may only depend on these new drugs. These patients and a lot of people complained about the greedy of pharmaceutical industries and government for the expensive price, but they have not thought about how many efforts behind these new drugs.

In order to invent a new effective drug, it takes around twelve years of researching and testing. According to MedicineNet, “Only 5 in 5,000 drugs that enter preclinical testing progress to human testing. One of these 5 drugs that are tested in people is approved. The chance for a new drug to actually make it to market is thus only 1 in 5,000”. Governmental regulatory in each country are controlling the drug’s approval process. As an example, the Food and Drug Administration (FDA) in the U.S. requires seven steps before approving one new drug into the market. The first step is Preclinical Testing, which requires certain studies, laboratory, and animal studies done for the targeted disease. The first step usually takes around three and a half years to complete. The second step is the Investigational New Drug Application (IND), which requires companies to file an application to the FDA for drug testing on humans. The third step to the fifth step is Clinical Trials, the drug testing on healthy volunteers, which takes about six years to collect all the necessary data. The sixth step is submitting New Drug Application (NDA) to the FDA with all the information from the previous step. The NDA typically has more than 100,000 pages, and FDA needs an average of two and a half years to review and approve each NDA. The last step is Studies that collect information from patients who take the drugs that

already been approved by the FDA. The complete process for inventing a new drug and put into the market is more than twelve years. Moreover, the odds of success are extremely low, while only 1 in 5000 drugs can make to the market, the other 4999 drugs still cost the pharmaceutical industries almost the same efforts like the one successful drug when they were in the same stage.

Novartis, the Top Pharmaceutical Company

Thousands and thousands of pharmaceutical industries rose and fell since WTO passed the agreement of TRIPS. More or less, they all contributed to the improvement of medical technologies. However, Novartis, as one of the top 10 pharmaceutical companies in the world, has received more complains and even insults than praises from patients. It is all because of the new era of targeted oncology drugs it invented, Gleevec. Gleevec was invented in around 1996. It became available in the market since 2001. The reason that Gleevec causes so many controversies is the price. Gleevec has extremely high price around the world under the protection of TRIPS. It has a price of more than 2000 dollars in the U.S. and around 4000 dollars in China. The patients have to take the medicine for a lifetime in order to reduce the possibility of the recurrence of the disease. Obviously, Gleevec is barely affordable for most patients. Therefore, a lot of people were saying that Novartis is too greedy for setting such an expensive price, and it has patent protection until 2016. Some people even accused Novartis "Murder" because low-income patients cannot do anything but wait for death while Novartis has the cure for them. However, those people may not know that Gleevec is called a new era drug because it has completely changed the treatment for the disease of Chronic Granulocytic Leukemia. It took more than 15 years for Novartis to create Gleevec. People can hardly see the huge amount of money and effort behind the expensive price. Patients' surviving rate has increased from 50% to more than 90% after taking this drug. Moreover, it is also effective for other cancers like

Gastrointestinal stromal tumors, and it has won the International Prix Galien prize, the Pharmaceutical “Nobel Prize”, for ten times with different versions. Gleevec has been saved uncountable lives undoubtedly.

Gleevec was the very first successful drug that brought Novartis worldwide reputation and profit. Although Gleevec caused some controversies, it did contribute a lot to the medical area. Novartis has never posted the particular cost for inventing the Gleevec, but we can get some sense from the cost that Novartis put on new medicine researching and testing every year.

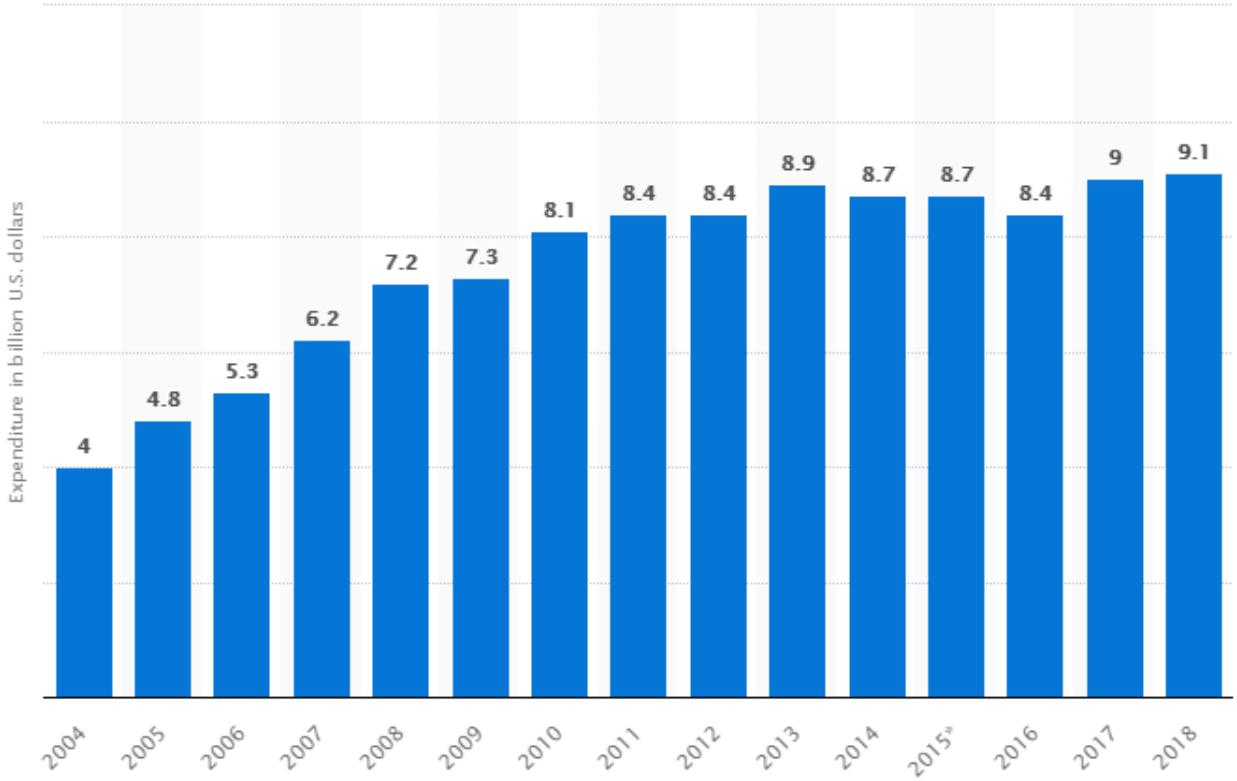

Figure 1

As figure 1 indicates, Novartis kept increasing the cost of their researching and testing these years. Novartis has become the pharmaceutical companies leading the world that put the largest money in researching and developing new drugs, and Novartis ranked fifth in the top 250

companies with the largest R&D investment in the world in all fields. The success of Gleevec encouraged Novartis to put even more effort and resources into designing new medicine. However, more than six big projects of new medicine designing have been stopped in Novartis since 2016. Once the new project stopped, the cost of the project could not be recovered because that new medicine may never appear in the market. For the same reason, the success of Gleevec did not come from anywhere. It was based on a series of failed projects, and part of the cost of research and development from those failed projects was naturally passed on to Gleevec. Meanwhile, Gleevec entered the market in 2001 and has patent protection until 2016, which gave Gleevec less than 20 years to recover the cost because the patent protection starts whenever the medicine is registered. Therefore, partial reasons for the expensive price of Gleevec seem reasonable and understandable. What especially valuable is that Novartis has not stopped progressing and making efforts on new medicine researching and designing. After Gleevec, Novartis has successfully invented more than 20 different medicine include Tasigna, Sandostatin, Afinitor, Revolade, Tafinlar, Votrient, and Kisqali that are effective as the treatments for different kind of cancers. Nowadays, Novartis has already become the biggest pharmaceutical company that owns the most robust cancer product lines in the field of oncology. It is seen as the hope to conquer more and more different cancers in the future. Besides, Novartis also put efforts into the development of vaccines and animal health. It also funded public research with other industrial and academic partners. Moreover, Novartis is working on a project to test a video visiting clinic for the patients. The patents that Novartis earned did not just make the company or the leaders in Novartis rich, they became the backing and motivation for Novartis and other pharmaceutical companies to keep working on the new medical technologies development and new medicine designing in the future.

The Struggling for Small Pharmaceutical Company

Unfortunately, not all pharmaceutical companies are as successful as Novartis. While people are either complaining or enjoying the most advanced research results from those successful medical companies, a lot of pharmaceutical or chemistry companies are also trying to survive and contribute to the development of medical progress. There are a bunch of pharmaceutical companies go bankrupt every year either lack enough money for further researching and new medicine designing or cannot recover the cost even they may successfully produce some new drugs.

Orexigen Therapeutics is a typical example of a pharmaceutical company that had not recovered the cost that is spent on researching and testing. Orexigen Therapeutics funded in 2002 and had been researching and developing new drugs in the primary care field. After working hard for a long time, a weight-loss drug has been successfully invented. It received approval from the FDA and got patent protection for 20 years. Meanwhile, it became a prescription drug for treating obesity. Everything seemed so good for Orexigen Therapeutics. It invented effective drugs and put it into the market after so many efforts. They did not set the high price for the drugs and it was affordable for almost all needed patients. However, things did not go well for Orexigen Therapeutics after marketing the drug. There were still more than 25 million dollars of debt remains when the due date came. Orexigen Therapeutics had no choice but announced bankruptcy in 2018. The future for Orexigen Therapeutics is unknown, it may get lucky if other big pharmaceutical companies get interested in acquiring it. Otherwise, Orexigen Therapeutics has no other way but only sells the patent it got for the drug.

The weight-loss drug that Orexigen Therapeutics invented is effective and patented. The main reason that Orexigen Therapeutics go bankrupt is that Orexigen Therapeutics could not

recover the cost before the debt was due. The researching and testing have cost Orexigen Therapeutics too much. When the weight loss drug was finally invented and tested, it brought up the only hope for Orexigen Therapeutics. Unfortunately, the profit it made cannot fit the cost that Orexigen Therapeutics spent. When the obesity patients enjoy the effective weight loss drug that Orexigen Therapeutics, they may not notice that the affordable price may cost the inventor bankruptcy. However, no matter Orexigen Therapeutics will be acquired or selling its patent, the weight loss drug succeeded, and it will keep helping obesity patients in the future. Orexigen Therapeutics may be forgotten one day, but the contribution it made for the medical improvement will not be.

TRIPS in Developing and Developed Countries

In addition to the direct drug price designer of pharmaceutical companies, the policies of various governments have become the target of many people who slammed for low-income patients. Although TRIPS was finalized among all WTO members in 1994, there are a lot of countries joined the WTO after 1994. And those countries negotiated with WTO about TRIPS specifically when they signed up. Therefore, not all TRIPS policies have been fully applied for the countries joined WTO after 1994. And India signed a very special agreement in 2005 when it officially joined WTO. However, that directly caused the comparison between the India government's policies and other developing countries' policies.

According to Anmol, TRIPS is implemented very well in developed countries because most west developed countries have a well-established medical and insurance system. The patients in developed countries need to pay a monthly or annual fee to insurance companies in exchange for coverage for most cost in medical needs. Therefore, the costs of researching and development from pharmaceutical companies will not all passed to the patients who need the

patented drugs. The costs will be divided equally to all insured people through insurance companies. However, things are much different in developing countries. Most people in developing countries do not enroll in health insurance, and they have extremely low income compared with the people in developed countries. When they need patented medicine for their illness, how should they afford those extremely expensive prices? In this situation, the India government made its own special decisions for intellectual property laws. Before India joined WTO, the India government has already allowed all pharmaceutical companies to copy any drugs available, there was completely no patent protection for medical products in India before 2005. After India joined WTO in 2005, the agreement between WTO and India forced the India government to legislate the laws for patent protection in the medical field. However, the agreement does not mean a lot in the real situation in India. The laws that the India government set only provide a few weak protections to pharmaceuticals. The generic production market in India did not change too much after 2005. Therefore, whenever new drugs were invented and came to India, they always faced generic competition immediately. The price of these patented drugs has an unexpectedly low price comparing with other countries in this situation. For example, Gleevec costs only around 50 dollars in India while 2000 dollars in the U.S. and around 4000 dollars in China. As a result of that, the patients in other developing countries have a lot of desire and demand for generic drugs from India. The huge profit from the price difference even made someone trying to smuggle the generic drugs from India. Patients in other developing countries complain about their own governments' policies and hope their governments to do the same things as the India government. However, what India government did come with some costs, and these costs "killed" more patients in India than the extremely high price of the patented drugs did. And it will cost more and more for India patients in the future.

The most direct price is the proliferation of counterfeit drugs. Since the India government encourages any pharmaceutical companies to produce generics to fill the needs of all the patients in India, the government does not have enough energy to supervise all the processes. Especially these are generics, and the differences between them and real patented drugs do not have clear boundaries. In other words, the quality of generics is hard to control. According to Jyotsna, around 25% of drug markets are contributed by fake medicines. And it keeps growing as one of the highest growing markets in India. Some fake medicines are just not effective for the diseases, but some fake drugs have no differences comparing with poison. Those fake medicines have already killed thousands of patients in India. Moreover, smugglers brought these fake drugs to the developing and undeveloped countries in Asia and Africa for the profit, and they killed more patients outside India.

Other downsides from the weak protection of patent for pharmaceutical products damage more for the future in India's medical improvement. Because of the weak protection and generic competitions, drugs inventing companies in other countries refuses to cooperate with Indian pharmaceutical companies in any researching includes designing new medicines. Also, these companies have joined forces with WTO to pressure the Indian government, which causes new drugs to enter India far later than other countries. According to Anmol, the delay for the new drugs in India usually takes 5 to 7 years. Therefore, patients in India have nowhere to buy new medicines during this period. Most importantly, since generics are the huge market in the medical field in India. Pharmaceutical companies have much less motivation in researching and designing new medicines. The innovation of new medicines in India is the bare minimum. The patients in India seem to enjoy the low patented medicines price, but they have lost more than they could ever think about. They are losing the hopes for inventing new medical technologies

and conquering incurable diseases, and they are losing the future for their next generations. Nothing will change in India unless the intellectual property laws change. Once the drugs development and innovation get patent protection from laws, more and more talented researchers will appear. Then the medical technologies development in India can be back on track.

Ethics Perspectives Analysis

The conflict between low-income patients' needs and long-term goals for pharmaceutical companies could be read through different perspectives. From Kantianism and Rule Utilitarianism perspectives, pharmaceutical companies have the right to set up a high price for them to recover the cost they spent in the researching based on the TRIPS that WTO passed. However, it is kind of tricky from the perspective of Act Utilitarianism. To achieve the greatest good for the greatest number of people, the patients' side could be reasonable because there are too many low-income patients who need low price patented medicines. However, the action that pharmaceutical companies take could benefit more for most people in the future. In other words, it depends on the timing perspective to look at this conflict. Giving low price patented medicine to the patients may fit the needs for now, but without enough funding and motivations, pharmaceutical companies can hardly put effort into researching and inventing new drugs. The future of the human medical situation will be ruined. Therefore, protecting the intellectual property for the inventing pharmaceutical companies is reasonable and beneficial from most ethics' perspectives.

Conclusion

Since history has been recorded, humans seem to be constantly improving their living conditions, achieving economic goals and distributing wealth through the wars were filled with

thousands and thousands of history books. Human society always needs to use scare resources to produce valuable goods and distribute them among different people through wars. However, the greatest impact on the economy and even on human living conditions in recent centuries is technological advancement. After nearly a few centuries of testing, technological advancement has become the most dependable engine for economic growth and the best way to eliminate war. Most people see it as the hope of the whole human society. In order to protect and promote the hope of scientific and technological progress, people have made a lot of effort, and the longest and most effective attempt in all the efforts is to establish an intellectual property system. It can be said that without the intellectual property system, there would be no capitalism, there would be no industrial revolution, let alone the light of human civilization such as constitutionalism and globalization. And of course, also in the medical area, people would be still suffering different terrible diseases that nobody thought can be cured one day.

Although the price of patented drugs cannot drop immediately and many low-income patients in developing countries are still struggling to afford the medicines they need, things are getting better. Governments are trying to change insurance policies to help more low-income patients, and pharmaceutical companies even provided direct help for low-income patients around the world with free drugs. In the future, the big pharmaceutical companies will continue to increase the investment for research and invention in new drugs. More and more small pharmaceutical and chemical companies will get motivated to devote to the researching for the development in the medical area even failed projects and tries are still more than the successful new drugs. But those tries will not be wasted, they will become valuable research experiences to help the innovation of the new drugs. And intellectual property protection helps the companies to recover the cost and motivates them to move further. Before the nineteenth century, human

medical technology advancement was a lack of success in the last few decades. After the nineteenth century, human inventors have begun to achieve star-like results in the medical field, and technological inventions are not only numerous but also fast. The establishment of intellectual property was an essential key to those impressive improvements. Because of intellectual property, human has conquered hundreds of diseases with effective treatments and have cured more than 12 deadly diseases in the last century. Therefore, protecting the intellectual property rights will keep helping humans to protect and promote the hope of scientific and technological progress, and provides the medical key benefits for the next generations in the future.

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