Global Public Health and Intellectual Property

Impact of IP on Public Health: The Developed Country Scenario

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Patents and data exclusivity affect health care costs even in developed countries and health care costs are rapidly increasing in those countries. Pharmaceutical product prices form substantial portion of health care costs and strong intellectual property protection is one of the major reasons for high health care costs. High drug prices affect patient access to medicines and thereby universal healthcare coverage. Left to market forces universal health care coverage, which is a fundamental obligation of states will remain an unaccomplished goal.

Keywords: Patents, healthcare costs, developed countries, intellectual property

Stronger IP protection, especially patent protection, data exclusivity etc., have been increasingly affecting the health care costs and health care coverage even in developed countries. Though the health care costs were largely borne by insurance companies, rather than by patients from their own pockets, the impact of IP on health care costs is a serious concern in these countries. Pharmaceutical price is the second major reason for high health care costs in the US and the third major reason in the EU.

The alarming rate at which drug prices are increasing is strikingly visible in the new technological fields. For example, patents in the field of genetic technology have recently led to controversies as they seriously affect patient access to drugs and diagnostic techniques, especially with respect to diseases like cancer. As a result, both the US and the Europe have recently witnessed severe protests from the doctors, patients and the public against high price of medicines, especially cancer drugs. A group of more than 100 experts in chronic myeloid leukaemia (CML) has come out in the open severely criticising the current pricing mechanism of CML drugs. The drug prices, they acknowledge, are 'too high, unsustainable, compromise access of needy patients to highly effective therapy, and are harmful to the sustainability of our national healthcare systems'.\(^1\) Similarly, in the UK, the unreasonably high price of Nexavar (£3,000 per month, whereas in India, where a compulsory licence was issued, the drug is available at £84 per month) has resulted in the NICE (National Institute for health and Clinical Excellence) rejecting Nexavar for use by NHS, based on its cost-benefit calculation.\(^2\) NICE has also rejected several other new cancer drugs on the ground that they are not cost-effective and this generated much hue and cry in the UK. The British government back-tracked and created a separate fund to pay for expensive oncology drugs. The government now plans to introduce ‘value-based pricing’ by 2014, with a system to price drugs not just for their efficacy but also for their ‘wider societal benefits’.\(^3\) As per Medco, a drug-plan manager, biotech drugs accounted for 70% of the increase in pharmaceutical costs in America in the year 2013.\(^3\) In a recent petition to the US Congress and the USFDA, over 300 petitioners have demanded the the Obama administration to force Novartis to cut the price of Glivec, which they say is too high and has risen six times since its launch in 2001.\(^4\) The major reason for this soaring drug price is market exclusivity enjoyed by pharmaceutical companies either in the form of patents or in the form of exclusive licences.

Impact of Patents on Health Care Costs in Developed Countries

The Unites States

The US, which is the world’s largest and least restricted prescription drug market and the global leader in new drug research and testing faces the most

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serious impact of high drug price due to the absence of government drug price control and public-private shared insurance system. The US’s reluctance to accept the notion that health care is an instrument of social justice was the reason for such a market based approach.

Senator Bernie Sanders has admitted that the US has the highest prices in the world for prescription drugs. While opening a hearing by the United States Senate, Committee on Health Education, Labour and Pensions (HELP), and Subcommittee on Primary Health and Agency on ‘The High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative’, he stated that ‘(t)he simple fact is that the prices of patent medicines are a significant barrier to health for millions of uninsured and underinsured Americans, and people die because of it’. According to him, in spite of the fact that America is the most innovative country in the world with the best universities, attracting the best minds from around the world, it has the least efficient health care system in the world. It spends more money per capita and a larger fraction of Gross Domestic Product (GDP) on the health care system than any other country and gets far poorer outcomes than the countries which are spending much less.

In Europe and many developed countries, universal health coverage shields patients from direct economic hardships of illness. But in the United States, patients have to pay an average of 20% of drug prices out-of-pocket (about $20-30,000 per year, a quarter to a third of an average household budget), and medical illnesses and drug prices are the single most frequent cause of personal bankruptcies. Illness or high medical bills contributed to 62.1% of all bankruptcies in 2007. Lack of health insurance results in as many as 44789 deaths per year in the US – more than those caused by kidney disease (42868). Even Americans with insurance find out-of-pocket costs difficult to pay. Many families with continuous coverage found themselves under-insured, responsible for thousands of dollars in out-of-pocket costs. Income loss due to illness was also common, but nearly always coupled with high medical bills. The extension of monopolies in an aggressive way also has an adverse impact on the behaviour of the reimbursement agencies and they either shift huge costs to others or find ways to limit access to treatment. There is also the problem of access being denied due to the decision of a rights-holding sole provider not to accept particular health insurance or not to permit other laboratories to offer testing that has prevented second-opinion testing.

A medical bankruptcy study in the US indicated that the US health care financing system is broken, and not only the poor and uninsured, but the middle-class families also frequently collapse under the strain of the broken health care system. The study revealed that medical impoverishment, almost unheard of in wealthy countries, is a reality in the US.

In the US, extremely high prices are a reflection of the ‘free market economy’ and the failure of government and insurers to more actively negotiate pricing for pharmaceuticals, in contrast to practices in other parts of the world. This contributes to the very high cost of health care in the US, estimated at $2.7 trillion in 2011, or 18% of the US GDP, compared to 6-9% in Europe. This increased expenditure does not add demonstrable benefit to US patients. However, hopes that the fundamentals of a free market economy and market competition will settle drug prices at lower levels have never been fulfilled. The Patient Protection and Affordable Care Act (PPACA) or the Affordable Care Act (ACA), aimed at health care reform, was signed into law on 23 March 2010 and will come into full effect only by 1 January 2014. Its implications on the health care costs are yet to be known.

Europe

Despite its larger population and more encompassing insurance coverage, Europe’s share of global pharmaceutical sales was ten percent less than that of the United States. The difference is mainly attributable to the higher drug prices in the US. For many of the top-selling drugs, the wholesale price in Germany or in the United Kingdom. The retail prices paid by the consumers or their insurers are two to four times higher when compared to other countries. Therefore, European-based pharmaceutical companies often seek market authorization first in the United States, despite the FDA’s international reputation for rigorous review.

The health care mechanism in the Europe is better administered (when compared to that of US) giving more respect to sanctity of human life. However, total expenditure on health care has risen considerably over the past twenty years across EU Member States, both in absolute terms and as a share of GDP. The level of total health expenditure steadily increased during
the 1990s and continues till today, to varying extents in each Member State. Health expenditures are increasing at a faster rate than GDP across EU Member States.\textsuperscript{13} Pharmaceutical expenditures are the third largest component of health expenditures, following hospital and ambulatory care spending in the European Union.\textsuperscript{14} Generic prices average about 25\% of the originator price, for one to two years following patent expiry.\textsuperscript{13}

A Comparison of the Approach of Different Developed Nations to the Patents in New Fields of Technology and Access to Medicines and Diagnostic Methods

Extremely high prices are common in the cases of pharmaceutical products or diagnostic techniques which rely on new technologies like genetic technology. In such fields, the practices of extending patent scope to subject matter hitherto not patentable, and allowing broad patent claims, have promoted patent monopolies in relation to undesirable fields of technology. In fields like genetic research, patent protection does not promote research and innovation, for the reasons that the Federal Government is the major funder of basic genetic research and scientists, generally, are driven by factors such as career advancement, desire to advance understanding, improving patient care through new discoveries, etc.\textsuperscript{11} Still unscrupulously broad patents are being promoted in this field in the US.

The situation is considerably different in the European Union. In 1998, the EU passed a Directive (98/44) on the Legal Protection of Biotechnological Inventions, requiring all of its Member States to implement laws enabling the patenting of human genes. But most Member Countries were very slow in giving effect to the Directive and different countries handled the issue differently. This was because they considered it a compromise between the demand for broad patent protection over new genetic technologies and the concern over the sanctity of human life.\textsuperscript{15} To meet its obligations under the Directive, France amended its bioethics law permitting patenting of genes.\textsuperscript{16} Simultaneously, in order to compensate it, the French government also expanded its compulsory licence regime to cover diagnostic tests. Only in 2006, the last of the Member States implemented the Directive.\textsuperscript{15}

The commercial strategy used by Myriad Genetics to gain market exclusivity in the US, Canada and the EU revealed the fundamental differences in the attitude of these countries/regions towards patent access to the benefits of new technologies. Myriad Genetics owns the patents for both BRCA genes and their mutations for breast, ovarian and some other cancers associated with BRCA1 & 2 genes. The research was supported in part by the National Institute of Health (NIH) grants and the National Institute of Environmental Health Sciences. NIH investigators, who were listed coinventors, assigned administration of those patents to the University of Utah. The University of Utah in turn, gave exclusive licence on the BRCA patents to Myriad. Thus, in effect, Myriad controls the patent rights and became the sole-provider for both BRCA1 and BRCA2 full-sequence tests in the United States.\textsuperscript{17} When Myriad introduced its test in the late 1990s, other laboratories had already been performing BRCA1 and BRCA2 tests using other methods. Once Myriad obtained its patents, it attempted to eliminate BRCA testing at competing laboratories by sending cease-and-desist letters.\textsuperscript{15} Myriad’s commercial strategy was successful in the United States.

Myriad’s patent has a history protracted litigation in the US. Gene patents were highly controversial in the US and the concern over it aggravated when the patent owners started enforcing its exclusivity uncompromisingly. Clinical pathologists were the most affected, as unlike the practices of other doctors, their medical practice of offering clinical diagnostic services was subject to patent law. In 1998, University of Pennsylvania's Genetic Diagnostic Laboratory received cease and desist letters on the basis of patent infringement from Myriad. Myriad also requested clinical pathologists to stop testing patient samples for BRCA. Thus, the Association for Molecular Pathology was compelled to challenge Myriad’s patent, along with the University of Pennsylvania and researchers from various universities. They challenged the claim on isolated patents, diagnostic methods etc., in seven of Myriad’s twenty three patents on BRCA1 and BRCA2. While the District Court invalidated all the contested claims, the Federal Circuit reversed that decision. The Supreme Court on a writ of certiorari vacated the Federal Circuit decision and remanded the case back to it to decide in the light of Mayo v Prometheus. Federal Circuit again upheld the patent eligibility of Myriad’s claims. On a second petition to the Supreme Court, the Court held that ‘a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent
testing without payment to Myriad.

The UK has adopted the strategy of ignoring gene which is charged directly to the patient in question. Often for specialist services for overseas patients, except for a very small percentage of private testing, commissioned under the NHS payment arrangements, services across the UK. The majority of this testing is particular disease areas and offer these specialist regional area. They also tend to specialize in testing used to provide genetic services for their laboratories in the UK that carry out the genetic Practitioners or consultants. The 25 regional genetics laboratories in the UK that carry out the genetic testing as many scientists believed that genes are not inventions. They consider that the discovery of the existence of a gene and the determination of its biological function are basic scientific facts and not the application of general scientific knowledge to develop particular products.

In Canada, the province of Ontario was the first to put up a serious fight against Myriad’s highly monopolistic attitudes. When the Ministry of Health was accused of infringing Myriad’s patents in Ontario, by funding directly or contracting with others, to perform genetic services, and the Ministry was asked to direct all laboratories to cease performing patented genetic testing, the Ministry categorically stated its policy: ‘It is the Government’s position that predictive ovarian and breast cancer tests should be available to women who require them’. It took the stand that payment to hospitals for the purpose of providing these services do not constitute infringement of any valid claim of patent. In a press statement the Minister stated that ‘monopoly pricing of a whole new category of diagnostics’ threatened publicly funded healthcare and equitable coverage. The threat by the US Ambassador to Canada indicating that the US Government was considering trade sanctions against Canada under the Trade Act of 1979 only hardened the government’s position. Myriad’s strategy exposed it to media criticism for its bullying tactics. Finally, Myriad decided to give up on Canada market. Ontario and other provinces sent clear message that Myriad’s commercialization strategy will not work in Canada. Canada’s attitude towards an exclusive licence over JAK2 gene to Warnex, a Canadian company, also was similar.

**Factors Contributing to Increased Healthcare Cost**

Various factors contributed to the high drug cost in developed countries. One common strategy of extending market exclusivity resorted to by patent owners is to obtain additional patents beyond the original patents that protect the drug’s underlying active ingredient and disease targets. These ‘secondary’ patents simply protect peripheral features of the product (such as a tablet’s coating), metabolites or alternative crystalline forms of the product, or

eligible because it is not naturally occurring’. At the same time the Federal court in Sydney upheld the validity of Myriad’s patents in last February, before the decision of the US Supreme Court.

However, the health care system in the European Union is considerably different from that existing in the US and when Myriad attempted the same business model in Europe it had a different experience. The Myriad business model faced strong resistance in the Europe. Unlike in the US, the state controlled health care system and insurance schemes, along with the sanctity attached to human life made them react differently.

Although much of European patent policy is set at the EU level, the health care systems are administered by national governments. Therefore different members responded differently to the Myriad’s commercial strategy. Along with the concern over the costs of genetic tests—such as BRCA1 and BRCA2—they also faced with patient and researcher concern. In France, the Ministry of health and the Ministry of Research planned a joint strategy to have the clinics affected by Myriad’s patent to commence an opposition proceeding against the patent at the EPO. Under European patent practice, the launching of an opposition by those directly affected by a patent was a way of weakening the position of the patent holder enough to make the patent holder start to negotiate a licence. The two ministries decided to offer public support for the opposition of the Institut Curie and two other clinics that wanted to provide BRCA1/BRCA2 diagnostic tests.

In the UK, almost all genetic diagnostic testing is carried out by the National Health Service (NHS), and not by private companies. Patients used to be referred for genetic testing and genetic counselling by General Practitioners or consultants. The 25 regional genetics laboratories in the UK that carry out the genetic testing used to provide genetic services for their regional area. They also tend to specialize in particular disease areas and offer these specialist services across the UK. The majority of this testing is commissioned under the NHS payment arrangements, except for a very small percentage of private testing, often for specialist services for overseas patients, which is charged directly to the patient in question. The UK has adopted the strategy of ignoring gene patents and the NHS continues to provide BRCA testing without payment to Myriad.

Other EU Members also followed similar strategies. Thus Myriad’s business strategy failed miserably in Europe. It also clashed with the scientific communities’ attitude towards gene patents and genetic testing as many scientists believed that genes are not inventions. They consider that the discovery of the existence of a gene and the determination of its biological function are basic scientific facts and not the application of general scientific knowledge to develop particular products.

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methods of use (such as a method of treating disease). In the pharmaceutical sector, this practice is called ‘life-cycle management;’ it is also sometimes referred to as ‘evergreening.’ Enactment of laws which have the effect of increasing the effective patent life, lowering of patentability standards, extension of patent protection to ineligible subject matter due to industrial compulsion etc., also have strengthened the monopolistic powers and resulted in the escalation of price of pharmaceutical products. Various methods are used to extend effective patent life in the developed countries due to the extensive lobbying by drug developers. They include patents on new compounds, new uses of old compounds, methods of heat stabilization, the use of gel tabs and enteric coatings on pills, fixed dose combinations, and countless minor improvements in products receive patent protection, exclusive rights to test data, orphan drug exclusive marketing rights, and other legal monopolies.

Apart from these, anticompetitive activities pursued by the branded pharmaceutical companies such as pay-for-delay settlements resulted in prevention of generic entry to the market and thereby increased drug-price. In the US, lack of proper regulation of drug price and predominance of private insurance companies in the health care system are the additional factors contributing to increased health care costs. Collectively these monopolies lead to high prices.

In the US, in 1961, Kefauver introduced a controversial bill designed to foster competition through additions to existing antitrust laws and compulsory licensing of drug patents to other manufacturers after an initial three-year exclusivity period. Kefauver’s bill was shelved after an initial debate on the Senate floor. As a result of the strong resistance from the pharmaceutical firms, which responded to the bill with warnings of stifled research, Kefauver’s bill was rewritten to focus on consumer protection and provisions concerning competition policy and drug prices were dropped. The US topped the developed countries in facilitating an almost unlimited support to pharmaceutical industry to have the most favourable atmosphere to garner maximum profit.

Since 1980s, the Congress has enacted a series of laws that have greatly increased effective patent life by branded drugs by either (1) extending the term of the original patent; (2) shortening the period of time consumed by clinical testing and regulatory review; and/or (3) granting ‘market exclusivity’ to drugs under certain circumstances. The cumulative effect of the Drug Price Competition and Patent Term Restoration Act of 1984 (the ‘Waxman-Hatch Act’), Orphan Drug Act, data exclusivity etc. is to extend effective patent life. In addition to these, the lowering of patentability standards, promotion of patent evergreening, widening the scope of patentable subject matter etc. contributed to the market exclusivity enjoyed by pharmaceutical patent holders. The decision of the US Supreme Court in Diamond v Chakrabarty which stated that the Congress had intended patentable subject matter to ‘include anything under the sun that is made by man’ played a historic role in expanding the scope of patentability and patentable subject matter. Though recently, the Supreme Court of the US has taken a more restrictive approach in determining the scope of patentability and patent eligibility through cases like KSR v Teleflex, Bilsky v Kappos, Mayo v Prometheus and AMP v Myriad, one should wait to see the impact of such decisions on pharmaceutical patents and access to medicines.

In Australia, rapidly rising drug price is attributed to the evergreening of patents. A study, relaying on publicly-available data on annual expenditure and prescriptions for the Pharmaceutical Benefits Scheme, concludes that the 10 drugs on which the government spent the most, accounted for about a third of total drug expenditures, and the 25 costliest drugs accounted for about half of total drug expenditures. The data also reveals that most high-cost drugs enjoy patent protection. This study analysed patenting activity around 15 of the costliest drugs in Australia over the last 20 years and identified a large number of patents encircling high-cost drugs in Australia. The majority of those patents relate to medicines that contain the Actual Pharmaceutical Ingredient (API) of the drug – either patents for a combination of the API with other pharmaceutical compounds, or patents for a delivery mechanism or a formulation for the API. Patents for a method of treatment using the API were also prevalent.

Another study was conducted in the Swiss canton of Geneva covering a 9 year period (2000 - 2008) over the impact of evergreening on health care costs in the region. This study revealed that the evergreening strategies of the pharmaceutical industry have been successful in the canton of Geneva with regard to several brand drugs facing intense price competition.
from generics after losing their patent protection. The generic competition and co-payment incentive implemented in Switzerland in 2006 contributed to an increasing replacement of brand with generic drugs and also reduced prices for brand drugs. However, this effect was found to be fully offset by the successful marketing of follow-on drugs.\(^{30}\)

Another interesting arrangement which contributes to high healthcare cost in the developed countries is pay-for-delay (reverse payment) agreements entered between branded pharma and generic manufacturers as per which branded pharma companies pay to generic firm in order to delay entry of the generic company into the market. In order to preserve their monopoly over weak patents which may be invalidated if litigation continues, they offer the generic challengers a share in the monopoly profit of the sales of the drug. Till recently the courts in the US were taking different stands on the issue whether such agreements fall within the scope of antitrust activities.\(^{31}\) Knowledge Ecology International (KEI) is of the view that the outcome of the case will have enormous impact on the availability of affordable generic medicines and the cost of treatment.\(^{32}\) A 2009 survey demonstrated that pay-for-delay settlements are on the rise.\(^{33}\) Early generic entry into markets promotes access to drugs at affordable price. Immunizing pay for delay agreements from antitrust scrutiny as the 11\(^{16}\)th Circuit has done, harms to public interest by allowing branded pharmaceutical companies to buy off generic competitors.\(^{32}\) The KEI argues that immunizing pay for delay agreements from antitrust scrutiny gives parties an incentive to settle rather than litigate the patents and permits branded pharmaceutical companies to protect unwarranted monopolies over products which do not promote progress of science and do not represent true innovation. The case is now settled by the Supreme Court of America finally concluding that ‘reverse payment settlements such as the agreement alleged in the complaint before us can sometimes violate the antitrust laws’.\(^{34}\) However, the Supreme Court was declined to hold that reverse payment settlement agreements are presumptively unlawful on the ground that ‘the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payers’ anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification’. This means that each case of pay-for-delay settlement has now to be litigated by the FTC to get it declared as anti-competitive. It is not sure to what extent this decision is going to curtail anticompetitive practices preventing early generic entry to the market.

Immediately after the decision of the US Supreme Court, the European Commission also came up imposing penalties on parties for the pay-for-delay settlement in the Europe. On 19 June 2013, the Vice President of the European Commission responsible for Competition Policy, in his statement said that the EC has imposed fines totaling 145 million Euros on Lundbeck and some generic competitors for the anticompetitive settlement between them, by which Lundbeck paid the generic competitors for not competing with Lundbeck’s branded medicine for depression, the patent term of which was about to expire.\(^{35}\) He decreed the settlement stating that ‘all this occurred at the expense of patients who were deprived of access to cheaper medicines’ and it also harmed the public health systems, which for a longer period had to artificially bear the costs of an expensive medicine – one of the most widely prescribed antidepressants. He has added that in the UK once generic versions of citalopram did enter the market, prices dropped on average by 90%.\(^{35}\) Same is the case with the US. Early introduction of generics has been estimated to have saved the US healthcare budget about $1.1 trillion over 10 years.\(^{36}\) Pay-for-delay arrangements between pharmaceutical companies and generic companies may profit both companies, but financially hurt the national healthcare system and patients.\(^{1}\)

Another method used by the branded pharmaceutical companies to keep the generic companies away is to launch their own generics (called ‘authorized generics’) at low prices. Using this method, branded drug companies have diminished generic company profits, resulting in delays of access of generics and reduced competition.\(^{37}\) Delays of generic TKIs (Tyrosine Kinase Inhibitors) through ‘pay-for-delay’ or ‘authorized generic’ approaches may harm patients with chronic myeloid leukemia and should be avoided at all cost.\(^{1}\)

**Conclusion**

In spite of the fact that basic research and drug development is done with the financial support of various government agencies, private corporations
acquire the patents over them and fix exorbitant price for the drugs. No wonder pharmaceutical industry is one of the most profitable industries in the world.\textsuperscript{38} The reason for unaffordability of life-saving drugs and the bankruptcy resulting from medical problems even in the technology rich developed countries exemplifies the supremacy of market power over the basic human right to life. It is pertinent to note, in this context, the recent developments in the UN General Assembly. In the 23\textsuperscript{rd} session of the Human Rights Council, in the Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, the Special Rapporteur calls upon the States to shift from the dominant market-oriented perspectives on access to medicines towards a right-to-health paradigm in promoting access to medicines. He emphasizes that access to affordable and quality medicines and medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central elements for the enjoyment of the right to health.\textsuperscript{39} Therefore, to leave it to the trade forum – in which the intellectual property laws are allowed to be given predominance over human rights – to dictate international policy on right to health will be an unforgivable lapse on the part of international organizations concerned over the basic human rights, including right to health.

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5 In contrast to either state-run or coordinated social insurance systems found in other OECD countries, the United States combines private insurance with public financing of Medicare and Medicaid.


It did not remove the blanket prohibition on patenting human genes; but merely added a section that would permit the patenting of human genes for specific uses.

Cook-Deegan Robert et al., Impact of gene patents and licensing practices on access to genetic testing for inherited susceptibility to cancer: Comparing breast and ovarian cancers to colon cancers: Patents and licensing for breast, ovarian and colon cancer testing, Genetics in Medicine, 12 (4 Suppl) (2010) S15–S38.


The Drug Price Competition and Patent Term Restoration Act of 1984 (the ‘Waxman-Hatch Act’) was a legislative compromise between an expedited approval process for generic prescription drugs and the restoration of patent life ‘lost’ during the clinical testing and FDA review period for innovative branded drugs, also called ‘originator’ or ‘pioneer’ drugs.


For new drugs approved between 1980-1984, it was 8.1 years whereas the new molecular entities approved in the late 1990s benefited not only from extensions under Waxman-Hatch, but also from the combined consequences of PDUFA and FDAMA and their patent life got extended to 4.4 to 5.9 years increasing the effective patent life to 13.9-15.4 years.


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