

Free Trade Agreement Between the USA and Thailand Threatens Access to HIV/AIDS Treatment

July 2004

Introduction

'I think that the main factor that helps me to recover and survive is medicine.'
(A patient in the Oxfam-funded Program for HIV Prevention and Treatment (PHPT) in Chiang Mai)

Access to HIV / AIDS medicines makes a huge difference to the lives of infected people and their families. Not only do these medicines help people live longer, they also greatly improve the quality of their lives, reduce the stigma and discrimination that they might experience, and enable them to contribute to the economic and social welfare of their families, their communities, and their countries as a whole. Thailand is a positive example of a developing country that has developed effective HIV / AIDS treatment programmes, with beneficial results for its population. It has a health-care system that can deliver antiretroviral therapy and other treatments to those in need. And thanks to the availability of affordable generic medicines the government is able to offer some key HIV / AIDS medicines to around 30,000 people, with plans to scale up the programme in coming years.

But the future of the treatment programmes could be seriously threatened if the USA succeeds in pressurising Thailand to accept stringent new intellectual property (IP) standards in the bilateral Free Trade Agreement (FTA), the negotiations for which were launched on 30 June this year. The Thai programmes lack some important medicines that are vital for scaling up treatment, but which are currently patented and priced out of reach of the government, NGOs, and most patients. Currently, the Thai government has, for example, the option of issuing a compulsory licence to over-ride the patents and authorise domestic production or import of affordable generic versions of these medicines. But if the USA gets its way in the FTA negotiations, such options

may be closed down. Recent FTAs between the USA and developing countries such as Singapore, Chile, and various Central American countries, contain intellectual property standards that :

- exceed the already damaging standards incorporated in the intellectual property rules of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS);
- prevent or delay the introduction of affordable generic medicines, by restricting or limiting the use of public health safeguards in the TRIPS Agreement ;
- undermine implementation of the 2001 WTO Doha Declaration on TRIPS and Public Health that reconfirmed the primacy of public health over private patents, and the rights of governments to use the TRIPS public health safeguards to protect public health and promote access to medicines for all.

The incorporation of similar 'TRIPS-plus' standards into the US-Thai FTA could seriously hamper Thailand's HIV / AIDS programmes, depriving thousands of people of effective treatment. Oxfam believes the USA should support Thailand's HIV / AIDS programmes, rather than undermine treatment by seeking stronger intellectual property standards through a backdoor bilateral trade agreement.

HIV/AIDS in Thailand

An estimated 695,000 women, men, and children are living with HIV / AIDS in Thailand, and around 290,000 people have died of AIDS since the outbreak of the epidemic. There are around 29,000 new infections each year, and of these cases approximately 4,200 are children. Access to affordable medicines is therefore a critical component of the government's strategy to treat those in need, and prevent the spread of the epidemic.

In recent years, the Thai government has taken some important steps to contain the epidemic, including the introduction of a strong preventative programme promoting condom use, provision of medicines to prevent mother-to-child transmission, and a treatment programme which currently provides HIV / AIDS medicines to 30,000 people. The government is planning to scale up treatment to reach all the 96,000 people who currently need antiretroviral medicines (ARVs).

'The quality of life has improved for all of us in every aspect after joining the project.'

'We can show our faces and confidently walk out of our home to meet people.'

(Patients in the Program for HIV Prevention and Treatment (PHPT) in Chiang Mai)

The treatment programme has been possible because the government has been able to manufacture affordable generic versions of some of the vital HIV / AIDS medicines recommended for first line treatment by the World Health Organisation (WHO). These generic medicines cost around ten times less than the brand-name versions. Local generic production of these HIV / AIDS medicines has been possible because the drugs were invented before Thailand introduced product-patent protection in 1992 and were therefore not patented in Thailand.

However, treatment programmes are hampered by the lack of other essential AIDS drugs which were patented in Thailand after 1992 and which are too expensive for the government, NGOs, or most patients to buy. Merck's efavirenz is one of those drugs.

Under TRIPS rules, Thailand has the option of using a compulsory licence as a bargaining counter in negotiations with companies to induce them to reduce their prices, or as a last resort to over-ride patents and authorise production or import of cheaper generic versions of these drugs. It could also import patented drugs from other countries where they cost less, a process called 'parallel importation'. The right of Thailand and other WTO members to use these safeguards was reconfirmed in the landmark Doha Declaration on TRIPS and Public Health, agreed by all WTO members in 2001.

But if the proposed US-Thai FTA is similar to other recent US FTAs with developing countries, such safeguards will no longer be available to Thailand. The current price differences between generic and patented drugs in Thailand suggests that the prices of vital patented drugs for alternative first-line and second-line treatment, along with medicines for treatment of opportunistic infections, could be around ten times higher than would be the case without the FTA. High prices will prevent Thailand from improving and scaling up its treatment programmes, depriving thousands of patients of life-saving first-line and second-line drugs to treat AIDS and opportunistic diseases associated with it.

The Thai government's HIV/AIDS programme

One of the key elements underpinning Thailand's successful treatment programmes is a locally-produced generic three-in-one HIV / AIDS tablet containing stavudine, lamivudine, and nevirapine. This simple and effective three-in-one tablet costs ten times less than the patented versions of the same drugs made by Bristol-Myers Squibb (BMS), GlaxoSmithKline (GSK), and Boehringer Ingelheim (BI) respectively. The generic fixed-dose combination also increases patient compliance, because it reduces the number of pills to be taken each day: only one has to be taken, twice a day.

'I joined the project in 2002 with a CD4 count of 0,¹ and started taking antiretrovirals (ARVs). I get free ARV treatment from the project. Now I am healthy, with a CD4 count of 212. I have a better quality of life.'

(Male patient, aged 35 years, in the Chiang Mai project)

However, the government HIV / AIDS programme excludes some alternative first-line ARVs that are essential for people who develop side effects or resistance to the currently available drugs. For example, some patients develop adverse reactions to nevirapine, including liver and kidney damage, so they need to be given other drugs such as Merck's efavirenz. However, efavirenz is patented and is too expensive for the government programme. With efavirenz, the daily cost of HIV / AIDS medicines increases from 40 to 138 Baht.²

A comparison of some first-line AIDS drugs in Thailand shows that the prices of brand-name versions are between 5.6 and 25.8 times higher than the prices for generic versions. The cheapest generic combination costs 40 Baht per day, compared with the cheapest brand-name combination, which costs 252 Baht per day. Considering that the minimum daily wage in Bangkok is 170 Baht (140 outside the capital), the generic

¹ CD4 is a type of blood cell which is attacked by HIV. The count is used as marker for assessing the state of the immune system. As CD4 cell count declines, the risk of developing opportunistic infections increases. The normal range for CD4 cell counts is 500 to 1500 per cubic millimetre of blood.

² 40 Baht = US\$1

fixed-dose combination costs around a quarter of the wage, while the cost of the equivalent patented drug is almost one and half times that wage.

As Thailand scales up treatment, its need for alternative first-line treatments, and also second-line treatments, will increase. Drugs such as lopinavir and indinavir are recommended for second-line therapy, but they are all patented and therefore very expensive. For example, a bottle of lopinavir syrup (made by Abbott) costs 11,770 Baht, and one Kaletra tablet (lopinavir combined with ritonavir, made by Abbott) costs 100 Baht.

Improved second-line and third-line treatments such as this are obviously beyond the means of both treatment providers and patients in developing countries, including Thailand. As side effects and increasing resistance can be expected to follow treatment with ARVs, there will be a continuing need for new medicines until a vaccine or a cure is found. Yet under current global patent rules, a future cure may be available only to those who can afford high prices associated with patented products – which means mainly those in rich industrialised countries.

'I took stavudine, didanosine, and efavirenz. I felt better, and my CD4 count increased from 15 to 160. But unfortunately I became ARV-drug resistant and was admitted to hospital again with a CD4 of 10. The doctor changed my ARVs regimen to protease inhibitors (PI) class, which is expensive. So I had to move to the Chiang-Mai project in October 2003 in order to receive PI. Now my CD4 count has increased to 320.'
(A 40-year-old female patient)

The treatment programmes also lack certain vital drugs to treat opportunistic infections linked to HIV / AIDS. While ARV treatment reduces the incidence of opportunistic infections, treating those infections directly can also save patients' lives and reduce the number of hospitalisations. Thailand is able to provide treatment for cryptococcal meningitis, a fatal opportunistic infection, because it can produce a cheap generic version of fluconazole, a drug developed by Pfizer for which the patent has expired. But certain other medicines, vital for the treatment of other opportunistic infections, are under patent and therefore too expensive to be used as part of the government programme. For example, GSK's ganciclovir is needed to treat cytomegalovirus (CMV), a dangerous infection which can cause blindness and death, but because it is patented it is too expensive (2655 Baht per 500mg vial) to be included in the government's programme.

Patent barriers to treatment

Various factors limit HIV / AIDS treatment in Thailand, including insufficient financing for health services. But patents have also created an obstacle to treatment, and their impact is likely to get worse if the Thai government signs a Free Trade Agreement with the US government containing TRIPS-plus patent rules.

The big pharmaceutical companies argue that the high levels of intellectual property protection demanded by TRIPS, and the even higher levels sought in FTAs, will generate revenues to finance necessary innovation. The industry does indeed invest substantially in research and development (although such expenditure is only half the expenditure on marketing), but for medicines needed for both rich and poor countries such as antiretrovirals, companies recoup their expenses in the profitable market in developed countries. There is little private research into health problems specific to developing countries because these are not lucrative markets, a fact that is reflected in companies' lack of interest in developing microbicides which can prevent infection by

HIV and other sexually transmitted infections. Much of the basic research has been funded by public institutions, and research into HIV vaccines was ignored by companies until public institutions increased their investment. The social contract implicit in a patent (citizens pay more for medicines, but benefit from innovation in return) does not apply in the developing world.

Since 1985, as a result of complaints by the Pharmaceutical Research and Manufacturers Association of America (PhRMA) who claimed that weak patent protection was costing them millions of dollars in lost revenue, the Office of the United States Trade Representative (USTR) has pressurised Thailand to strengthen its patent laws. In response, Thailand amended its patent laws in 1992 to allow drugs to be patented, and extended patent life from 15 to 20 years even before it had any international obligations to provide and enforce patents. In just a few months' time, at the start of 2005, all remaining countries (with the exception of those least-developed countries that have not given away their entitlement to the extended deadline for compliance to 2016) will have to comply with TRIPS, thus forfeiting the possibility of producing or importing cheap generic versions of new medicines, except under a compulsory licence.

As permitted by TRIPS, the Thai patent law currently does allow compulsory licensing and parallel importation. The Thai government has so far declined to use these so-called 'flexibilities', despite pressure from Thai civil society to do so. This is in part due to pressure from the USTR. At least a quarter of goods exported from Thailand go to the USA, so the USTR has a strong advantage in negotiations with the Thai government. Although the Thai government has not yet used this option, it may need to do so in the future as costs of its treatment programmes rise. Moreover, Thai civil-society organisations have recently managed to use alternative legal means to revoke invalid HIV / AIDS patents on the ARV didanosine (ddI), produced by BMS.

Thai civil society organisations successfully challenge invalid HIV/AIDS patents

In a court case in Thailand, the plaintiffs, AIDS Access Foundation and HIV patients, alleged that Bristol-Myers Squibb (BMS) intentionally deleted the dose range of the formula for ddI, a vital HIV/AIDS medicine, after its patent application was publicised. This effectively broadened the patent scope to all drug strengths. In 2002, the court recognised that the removal of the dose range extended the patent protection beyond the scope of the initial application, and ruled that BMS must correct the Thai patent by adding the specific doses of the medicine covered by the patent. This court case set an important precedent for the legal definition of 'plaintiff' in the case of drug patents. Now, the status of plaintiff is not limited exclusively to the pharmaceutical industry but can also include consumers. The court's judgement was based on the concept of human rights and the right to health.

Four weeks later, a second court case was challenged by the Foundation for Consumers and AIDS patients. They argued that BMS's ddI patent should be revoked for three reasons. First, BMS applied for this product patent before the new amended Patent Act was officially enacted in 1992. Second, there was no novelty in this invention, because the information about this drug had been disclosed and it was already on the market before it had been patented. Third, this product development was trivial and thus does not qualify for the novelty criteria. During the court proceedings, BMS decided to terminate the case by renouncing this patent in Thailand. This has allowed the Thai government to begin manufacturing ddI tablets.

The case of ddI illustrates how drug companies can use the patent law to extend the scope of their patent. There is a danger that such successful challenges to patent abuse will not be permissible under the new bilateral trade agreement with the USA.

The patent rules in the proposed US-Thai FTA, if based on recent US FTAs including those with Singapore and five Central American countries, will finally close down such options for Thailand. While some developing country governments, such as

Malaysia, have issued compulsory licences in response to growing pressure from civil society and the opportunities opened up by the Doha Declaration, Thailand may be unable to do so if it commits to a stricter patent regime under a US-Thai FTA.

If the Thai government is unable to use compulsory licensing to negotiate lower prices or authorise production of cheap generics, it is unlikely that it will be able to afford patented alternative treatment (first-line, or second- and third-line) for those people who have adverse reactions or who develop resistance to the existing first-line treatment package. It is estimated that the incorporation of the alternative first-line drugs, plus second- and third-line medicines, into the Thai treatment programme at current patented prices, would double or even triple the cost of the programme. The more likely outcome is that the government will simply not be able to buy these drugs and fewer patients will have access to life-saving medicines.

The story of a male patient, 35 years old, in the Chiang Mai project

I joined the Chiang Mai project in 2002 with a CD4 count of 0, and started taking ARVs. I get free ARV treatment from the project. Now I am healthy, with a CD4 of 212. I have a better quality of life. I work with the network of people living with HIV (PLWAs) as a volunteer. Our network comprises ten volunteers and the groups of members in every level from sub-district, district, and province. We volunteers are happy to provide the counselling and home visits. I am very proud that we can physically and mentally support each other in the network. I have participated in the monthly meeting between patients, network of PLWAs, and health personnel, discussing treatment. Now I can work normally and earn 1,500 Baht per month from repairing motorcycles.

I heard about the US-Thai FTA from the network of PLWAs. I think the period of drug patent should be shortened, to help patients who cannot get access the expensive drugs. I do not want the Thai government to sign this FTA. I would like to tell the US government that the market-exclusivity of patented drugs will affect human health.

The content of US-FTAs

'FTAs with ASEAN countries will be based on the high standards set in the US-Singapore FTA, which we are aiming to complete this year, for action by Congress next year.'

(The White House)

The intellectual property standards in recent US FTAs with developing countries exceed even the already damaging standards of TRIPS, and threaten to block access to medicines. They also contradict the WTO Doha Declaration on TRIPS and Public Health which confirmed the rights of governments 'to use to the full, the provisions in the TRIPS Agreement which provide flexibility' to 'protect public health and promote access to medicines for all' . For example recent US-FTAs with Chile, Singapore, and some Central American countries, include the following TRIPS-plus provisions:

- New requirements for governments to extend patent protection beyond the 20-year period required under TRIPS. Extending this monopoly period will further delay the introduction of affordable generic medicines.
- New restrictions of the grounds for compulsory licensing. This could limit governments' ability to bargain for cheaper patented drugs, or promote competition by generic producers to reduce prices and increase access to medicines.

- New provisions giving patent holders the means to block parallel importation. This will limit governments' ability to import patented medicines sold on foreign markets at lower prices.
- New provisions preventing regulatory authorities from allowing generic companies to use clinical trial data generated by brand-name companies in order to obtain marketing approval for generic equivalents. This will delay or prevent generic competition, even in the absence of patent barriers and even if a compulsory licence is issued. Unable to rely on originator data, generics companies would have to repeat unnecessary, time-consuming, and costly clinical trials in order to obtain marketing approval; many would choose not to enter the market rather than repeat the testing. In the event that a compulsory licence were issued, there would simply not be enough time for generics producers to repeat the tests and obtain marketing approval. Because there would be no authorised suppliers of generic equivalents, compulsory licensing would not be a viable policy tool.
- New provisions preventing national drug-registration authorities from registering generic versions of drugs until after the patent expires. Under some recent US FTAs, generics producers cannot obtain marketing approval at any time during the patent term, even if they generate their own test data, and even if a compulsory licence is issued. This prevents the effective use of compulsory licensing, because no suppliers of generics could obtain marketing approval, and it delays the availability of affordable generic versions of new medicines until well after patent expiry.
- Grounds for revoking a patent are limited. This makes the overturning of patents, as in the case of dDI above, more difficult.

Conclusion

Oxfam shares the concerns of Thai NGOs that a Free Trade Agreement with the USA, containing unnecessarily high intellectual property standards, will seriously undermine future access to affordable medicines in Thailand. Oxfam urges the USA to refrain from pressurising Thailand to implement TRIPS-plus measures in the FTA, and instead to give its maximum support to the expansion of the Thai AIDS programme.

The case of HIV/AIDS in Thailand illustrates how unnecessarily strict intellectual property protection could block access to medicines. But the problem is not limited to this disease. Thai people need other medicines to treat diseases such as pneumonia, gonorrhoea, and cancer. The rising incidences of resistant infections and of chronic disease also require new, effective, and affordable medicines. Many of these medicines are, and will be, under patent and therefore too expensive for those who need them.

Oxfam therefore supports the call from Thai civil society organisations for the Thai government to make maximum use of compulsory licensing to allow poor people to gain access to affordable generic medicines, and to reject new TRIPS-plus measures in the US-Thai FTA. Thailand already complies with the TRIPS Agreement, so there is no need for additional intellectual property provisions in an FTA – except to provide short-term commercial benefit to big pharmaceutical companies which will be to the detriment of thousands of Thai people.

ANNEX: The relationship between five US FTAs, TRIPS, and the Doha Declaration ³

The Doha Declaration was unanimously agreed by WTO members – including the USA – in November 2001. It affirms the right of all WTO members to use the safeguards and flexibilities in TRIPS to promote ‘access to medicines for all’ and constitutes a commitment to favour public health over patent rights. The US Congress subsequently enshrined the Doha Declaration in the mandate granted to the USTR for negotiating FTAs; the Trade Act of 2002 instructs the USTR to respect the Declaration in all trade negotiations. But none of the FTAs refers to the Doha Declaration. Instead, the USTR has consistently violated its mandate by negotiating TRIPS-plus provisions in FTAs – including those with developing countries – that limit and restrict the public health safeguards in TRIPS, and delay or prevent the introduction of affordable generics. All of the bilateral and regional FTAs are TRIPS-plus. The impact will be diminished availability of cheap generic versions of expensive patented medicines, a situation that will further reduce access to medicines, in direct contrast to the Doha goal of ‘access to medicines for all’. To assuage concerns about FTA patent provisions, USTR has negotiated ‘side letters’ on public health to accompany the Central America Free Trade Agreement (CAFTA) and other more recent agreements. But the side letters, which state that the FTAs should not prevent the Parties from taking measures to promote access to medicines or to implement WTO decisions regarding the TRIPS Agreement, have interpretative value only. They do not modify the agreements and are unlikely to offset the damaging impact of the binding TRIPS-plus provisions in the text that require countries to enact measures that will restrict their use of TRIPS safeguards and reduce availability of generics. Rather than accepting USTR assurances that side letters will protect their capacity to promote access to medicines, developing countries should reject FTAs that contain TRIPS-plus patent rules.

Agreement	Text	Comments
TRIPS (Annex 1C) 1995 and the Doha Declaration	The Declaration is used to interpret TRIPS, and it led to agreement to modify Article 31 of the TRIPS Agreement. Paragraph 4: ‘We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.’ Paragraph 6: ‘We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.’	The ‘Doha Declaration on the TRIPS Agreement and Public Health’ was adopted unanimously by all WTO members in November 2001, at the Fourth Ministerial in Doha, Qatar. It has interpretive value <i>vis-à-vis</i> the provisions in the TRIPS Agreement, as it was the result of unanimous agreement by all signatories. It recognises the right of all WTO members to use the TRIPS flexibilities and safeguards to promote public health, without fear of retaliation. Paragraph 6 of the Declaration contains a commitment to resolve the dilemma of WTO members that are too poor to afford expensive patented medicines but cannot manufacture their own drugs; a solution to this problem was agreed in August 2003, which WTO members are transforming into an amendment to the TRIPS Agreement. The Declaration also granted least developed countries (LDCs) an extended transition period for TRIPS compliance (until at least 2016). The Declaration represents a commitment to prioritise public health over patent rights, in recognition of the link between patent rights and high prices for new technologies and products, notably medicines. It was enshrined in the mandate given by the US Congress to the US Trade Representative when negotiating free-trade agreements; USTR is instructed by Congress to respect the Doha Declaration in all FTA negotiations.
North American Free Trade	NAFTA preceded the Declaration. NAFTA is TRIPS-plus.	NAFTA was passed before the Doha Declaration was adopted, but its patent

³ This table is a summary of a technical note produced by Oxfam entitled ‘Undermining Access to Medicines: Comparison of Five US FTAs’

Agreement (NAFTA)*⁴ (1994)		provisions are 'TRIPS-plus', in that it limits or restricts the TRIPS public-health flexibilities and safeguards. The following are TRIPS-plus provisions in NAFTA: it contains no public-interest objectives and principles, provides for extension of the patent term, and provides for protection of test data.
Chile* (2003)	The text does not mention the Declaration. The Chile FTA is TRIPS-plus.	The IP chapter of this FTA is TRIPS-plus in many ways. It undermines the Doha Declaration by eliminating or restricting the public-health safeguards in TRIPS. In negotiating this TRIPS-plus IP chapter, the USTR violated its mandate to 'respect the Declaration on TRIPS and Public Health'. TRIPS-plus provisions in Chile FTA: it contains no public-interest objectives and principles, provides for extension of the patent term, limits the grounds for revoking a patent, prevents registration of generics at any point during the entire patent term, and provides for test-data protection.
Singapore* (2003)	The text does not mention the Declaration. The Singapore FTA is TRIPS-plus.	The IP chapter of this Agreement undermines the Doha Declaration, eliminating or restricting the public-health safeguards in TRIPS. Provisions in the Singapore FTA that are TRIPS-plus: it contains no public-interest objectives and principles, provides for extension of the patent term (linking same to extension of the patent abroad), limits grounds for revoking a patent, provides patent holders with means to block parallel importation, provides for test-data protection, prevents registration of generics relying on originator test data during the entire patent term, and limits grounds for using compulsory licensing.
Central America Free Trade Agreement (CAFTA)* (2004)	No mention of the Declaration, although a 'side letter' on public health indicates that CAFTA should not prevent the Parties from implementing agreements reached on access to medicines at the WTO. CAFTA is TRIPS-plus.	The IP chapter of CAFTA undermines the Doha Declaration, eliminating or restricting the public-health safeguards in TRIPS. By negotiating the TRIPS-plus patent provisions in CAFTA, the USTR violated its mandate under Trade Promotion Authority to 'respect the Declaration on the TRIPS Agreement and Public Health'. Provisions in CAFTA that are TRIPS-plus: it contains no public interest objectives and principles, provides for extension of the patent term, prevents registration of generics relying on originator test data during the entire patent term, and provides for test-data protection.

⁴ An asterisk indicates that the FTA or provision is 'TRIPS-plus', meaning that it restricts or eliminates the flexibilities in the TRIPS Agreement

Free Trade Area of the Americas (FTAA)* (Deadline for completion January 2005)	The text does not mention the Declaration. Many of the bracketed provisions in the FTAA negotiating text are TRIPS-plus.	The IP chapter of the FTAA violates the Doha Declaration, by eliminating or restricting the public-health safeguards in TRIPS. The proposed FTAA zone encompasses many poor countries, including one LDC: Haiti. The Doha Declaration provides LDCs with an extended transition period – until at least 2016 – before they must comply with the TRIPS Agreement. Under the FTAA, Haiti would be required to comply with TRIPS-plus provisions well before that. Provisions in the FTAA negotiating text that are TRIPS-plus: it provides for patent extension (linking same to extension abroad), provides for test-data protection, limits grounds for using compulsory licensing, and prevents registration of generics during the patent term.
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