IN DEFENCE OF NATIONAL INTEREST

A REPORT ON UGANDA'S REFORM PROCESS FOR THE INDUSTRIAL PROPERTY LEGISLATION

COALITION FOR HEALTH PROMOTION AND SOCIAL DEVELOPMENT (HEPS UGANDA)
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COALITION FOR HEALTH PROMOTION AND SOCIAL DEVELOPMENT (HEPS-Uganda) In partnership with **PANOS EASTERN AFRICA**

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Special commendations go to the following for their contribution to the production of this report: Rosette Mutambi-Coordinator HEPS Uganda, Zawadi Kamango-Deputy Director PANOS Eastern Africa, Kitty Warnock,-ANOS London, Beryl Leach-Coordinator HAI Africa, Martin Foreman-PANOS London as well as staff of HEPS-Uganda and the entire health access coalition.

Edited by Shaban R. Sserunkuma,

Pre-press production and printed by **Hashnet Media**
(hashmedia@prontomail.com)

HEPS-Uganda (August 2003) Report No. 1

Foreword

The publishing of report is timely, given the events and growing relevance of intellectual property and public health, the report will serve as a policy and advocacy tool, now that Uganda is currently preoccupied with reform for its commercial laws, which includes the patent law.

More importantly, the publication comes at a time when the members of the WTO are preparing to converge in Cancun (Mexico) to negotiate various agreements and provisions including IP and health. In addition, most members states of the World Trade Organisation (WTO) are in the process of revising their laws to comply with the Trade Related Intellectual Property Rights (TRIPS).

To comply with TRIPS, however, patent legislation is being introduced in many countries where previously it did not exist. While the pharmaceutical industry argues that such policy is necessary to promote innovation, we believe that the impact will be to reduce competition, push up prices and limit access to drugs in the world's poorest countries.

There are alternative means of increasing access to medicines. These include compulsory licensing, where a patent is overridden in turn for payment of a royalty, and differential pricing, where poorer countries pay considerably less for a product than wealthier ones. However, such measures continue to generate controversy. While TRIPS remains the focus of intense international debate, within many countries there has been relatively little discussion of the potential impact of the agreement. Worse still, some countries like Uganda are causing worry among stakeholders by the apparent stampeding of the IP Legislation process.

Increasingly, legislators, healthcare providers, the media and other stakeholders are becoming aware that a debate on IP legislation is an essential part of the process of ensuring equitable access to health for all, particularly in developing countries like Uganda. This report explains the process of reform of the patent law and will trace the genesis of the process as well as stakeholder involvement, with a view to pointing out apparent pitfalls and recommendations to realign stakeholder involvement in the IP legislation process. The benefits from such an approach cannot be overemphasized.

Rosette Mutambi
Coordinator, HEPS-Uganda

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INTRODUCTION

Uganda is currently preoccupied with reforms for its commercial laws. The patent law is one of the laws under reform. A draft bill known as the Industrial Property bill is pending submission to cabinet at the time of writing. This report explains the process of reform of the patent law and traces the genesis of the process, stakeholders involvement, as well as the driving force for the reforms.

Background

The commercial law reform process commenced as far back as 1994 when the Uganda Institutional capacity Building project (ICB project) was designed[1]. But the idea had been floated in the country as early as late 1990 with the establishment of the Law Reform Commission to reform all the outdated reforms. Intellectual property laws were among laws for reform. This was in anticipation of the outcome of the Uruguay round of negotiations that were already underway.

The ICB project consisted of several components hosted under different ministries. The Ministry of Justice and Constitutional Affairs hosted the legal sector component. The Uganda Law Reform commission ("the commission"), a statutory body mandated to reform law in Uganda[1], commenced with law reform as a sub component of the legal sector component in 1995.

The reform process covered a number of laws divided into clusters. Commercial laws including intellectual property laws were among the clusters of laws to be reformed. Under the legal sector component, the Ministry of justice hired a team of consultants from Reid & Priest LLP of Washington DC to study the range of commercial laws, including patent law, and make proposals for reform. The team co-opted two Ugandan law firms to co-execute the task.

The team issued their draft report in 1997. The Commission reviewed the draft and made comments. The consultants came up with the final report in 1998.

The commission was able to carry forward the reform process with funding from USAID and the Justice Law and Order sector of the Ministry of Justice obtained in 2000 – 2001.

USAID also hired a consultant, Mr. Michael Hathaway from Nathan Associates

[1] The Law Reform commission was established by the Uganda Law Reform commission Statute of 1990.

of Virginia State, USA, to provide technical expertise to the LRC but he did not execute the contract owing to his " busy schedules." He was replaced with another consultant from Nathan Associates, Mrs. Judy Goans, in August 2001. The consultant helped to put together the first drafts for various laws including the patent bill.

The terms of reference for the consultant were:-

- To prepare a background paper covering a review of the relevant existing laws on corporate and individual insolvency including those with a bearing on the identified laws.
- To review and identify laws in line with international and regional commitments and undertake a comparative analysis of the laws and policies of other jurisdictions including countries whose economies are in transition.
- To identify outmoded laws and provisions relating to intellectual property and modify them so that they are up to date with other economic, social, technological and other developments that have taken place in the world.
- To guide consultative meetings and a workshop with selected key stakeholders constituted into a taskforce selected by ULRC and agreed to by the consultant.
- To propose and make recommendations on all laws studied and prepare a report incorporating all work done under the study.

LEFT OUT: *Access Coalition members, Health Advocates attending a meeting on health care in Jinja, Uganda.*

The state of IPR legislation prior to the reform process

Prior to the commercial law reform processes, Uganda had an IPR regime comprised in the following laws:

- The Patent Statute No. 10 of 1991
- The Copyrights Act, Chapter 81
- The Trade marks Act, cap 83
- The United Kingdom Designs (protection) Act, Chapter 84 (This law was enacted by the Ugandan parliament to protect UK designs in Uganda and it was part of the laws of Uganda.)

Most of these laws had been modeled on the UK legislation and were passed by the Ugandan Parliament soon after independence[2]. Apart from the Patent Act, which was enacted in 1991, these laws have not been amended and have been overtaken by developments in the international regime.

POLICY CONSIDERATIONS FOR REFORM

The reform of commercial laws was based on two policy considerations. The first one was the developments in international law and commercial discourse, which rendered Uganda's commercial law regime obsolete. The second one was predicated on the theory that these obsolete commercial laws were an impediment to foreign direct investment (FDI) and technology transfer. In the case of intellectual property law, the immediate policy consideration was that, being a member of WTO, Uganda was obliged to comply with the TRIPS agreement by reforming its IP law to conform to the minimum standards set therein[3].

However, the reason for the policy decision to reform the patent law ahead of the deadline is unclear. The TRIPS agreements gives least developed countries, up to 2006 to comply and up to 2016 for pharmaceuticals. Uganda, being one of the least developed countries still had three years (at the time of production of this report) and 13 years in the case of medicines to comply with the TRIPS agreement. Two reasons are suspect. The first one is the theory that was touted from the inception of the reform process, that stronger intellectual property is conducive for FDI and technology transfer. The idea of FDI and technology

[2] Uganda became independent in 1962.
[3] Speech by Hon Janat Mukwaya, Minister of Justice at the Consultative Workshop organized by ULRC; See Workshop report.

transfer sounds sweet to the ears of least developed countries. The mere mention of it was enough to attract the attention of the policy makers.

The other is perhaps the bilateral tool of technical assistance, which the US uses to convince developing countries to accelerate implementation of the TRIPS agreement, including TRIPS-plus provisions. Uganda is not insulated against this kind of pressure and influence. The technical assistance package in the USAID funding included consultants from Nathan Associates a consulting firm in the US. The choice of these consultants was made by USAID or at least in consultation with them. There was no provision for alternate local consultants. The ideas mainly floated by the various consultants and in built in the project funded by USAID was that there was no need to exhaust the transitional period because the country was losing out on FDI and technology transfer. The Uganda government was quick to embrace it and to believe that the earlier it reformed the sooner the country would see increased capital inflow.

Major players

From the inception of the idea to the formulation of the project, the main actors were government officials in the Law Reform Commission, other ministries particularly the Ministry of Finance and Ministry of Justice, as well as the consultants. The Registrar General's department in the Ministry of Justice, which is responsible for intellectual property matters, played a peripheral role in the reform process. Other major stakeholders, such as the National Drug Authority and Ministry of Health did not participate. International organizations, such as WHO, UNIDO, UNCTAD and WIPO, which have the mandate to provide technical assistance were never involved.

The consultants hired by USAID (Nathan Associates) seem to have mainly focused on compliance with international standards as the main objective of the reform process. Their review looked at the desired changes to facilitate businesses rather than the social economic needs of Uganda. The government of Uganda did not commission any independent study with local consultants to generate alternative policy considerations. In addition, the involvement of civil society was minimal and limited in the process of drafting the bill.

The reform process was premised on the commercial perspective right from the start. The government embraced the consultant's argument that TRIPS complaint patent law was necessary in order to attract foreign direct investment[4] and to boost economic growth. Due to the absence of an

alternative perspective, the commercial perspective took the day. Consequently, other policy objectives relevant to intellectual property protection such as public health were overshadowed.

The draft industrial property law was developed as a cluster in the whole range of commercial law under the project and was premised on the general ideas initially generated by the Reid & Priest consultants. Other stakeholders such as line ministries[5], specialized bodies and civil society got involved at the stage of making concrete provisions. These stakeholders were identified by the LRC in consultation with the consultant and the private sector trade policy capacity building project to constitute the taskforce generally on intellectual property laws. The industrial property bill was never given any special attention throughout the process.

The task force was first constituted in January 2001. Although a number of meetings took place thereafter, in effect the process started in August 2001. The stakeholder meetings were held between January 2001 and August 2001 but no concrete drafts were made. Draft bills were made in the period between August 2001 and January 2002. in all, nine drafts were in place and Seven of them were discussed at a stakeholder consultative workshop in mid January 2002.

This meeting, which the author of this report attended, lasted three days and all the seven bills were discussed with the consultant from Nathan Associates. The author's observation was that the volume of work was not commensurate with the time line taking into account the technical nature of the subject. On the whole it was a question of rushing through the bills within the time schedule sponsored by USAID. Again the Industrial Property Bill was never given separate attention. To the process architects, the draft bill was like any other bill.

The taskforce consisted of the institutions represented by individuals as shown in the annexure at the end of the report with the following terms of reference:

- To assist in identifying issues relevant to the stakeholders in the cluster
- To comment of the review of the existing law and study proposals from various ministries and organizations prepared by the consultants
- To present the views of the different sectors they represent on the proposed laws.
- To participate in the deliberations and reach consensus on the working

[4] Final Report on the patent Statute no 10 of 1991 submitted by the Consultants to Justice Ministry.
[5] Line ministries in this case were the Ministry of Health, Ministry of Trade and Industry, The Registrar General's department of the Ministry of Justice

papers and draft bills

- To discuss the proposals and recommendations to be presented at the consultative workshop
- To participate in the consultative workshop, and
- To discuss the final report within a timetable to be agreed upon.

The laws under consideration fall two categories as below:

(a) The existing ones that require revision. These include;	(b) The proposed new areas of legislation include:
• Patent Statute no 10. of 1991 • Trademark Act Cap 83 • Copyright Act Cap 81 • United Kingdom Designs (protection) Act Cap 84	• Geographical indications • Technovations • Utility models • Trade Secrets • Industrial property office

Model used

The draft bill was modeled on the Hong Kong Patent-Law. The reason for this choice was that to the researchers the Hong Kong legislation appeared more elaborated compared to the many pieces of legislation from different countries which researchers scanned through. The Kenyan Patent Legislation was also used. Both of these statutes were modified "to suit Uganda's circumstances." The Kenyan law was chosen because as a developing country, Kenya has just put its TRIPS complaint legislation in place and it was felt that Uganda could borrow some ideas. Although this legislation was a model for a public health sensitive legislation, some of its useful provisions were modified in drafting Uganda's IP Bill. The modifications were certainly made or at least influenced by the consultant from Nathan Associates and arguably reflected much of US interest.

EFFECTIVENESS OF STAKEHOLDRS PARTICPATION

While the stakeholders were involved in the process, the effectiveness of their contribution was not effective:

First, only one task force was constituted to consider the whole range of commercial laws mentioned above. Under this arrangement, it was difficult to make serious analysis necessary for the right policy decisions. The Commission maintains that the task force was subdivided into clusters (sub-committees)[6]. But some members of the taskforce do not remember belonging to any such sub-committees. In addition the available records do not indicate the constitution of those sub-committees other than mentioning them.

Second, the taskforce worked for a short period and with irregular attendance. According to some members of the taskforce interviewed, they held four to six meetings in all. Attendance was very poor and irregular save for the initial meetings, which attracted considerable enthusiasm from among the members. According to one of the taskforce members, this was largely due to lack of facilitation in terms of allowances, transport refunds and refreshments, which the Commission could not provide due to limited funding. Not withstanding this irregular attendance, meetings continued because the Commission had a time limit within which to accomplish its task. It is not possible that the stakeholders had considerable contribution to the seven drafts.

Third, the task force membership lacked expertise in the area of intellectual property rights law.

This could largely be explained by limited expertise in the country. However, even the few that are knowledgeable in IPR issues were not incorporated in the taskforce.[7] There were no initial training for taskforce members and it is doubtable that in a short spell of four months the team had through private study grasped substantial knowledge and skill to raise relevant concerns for consideration in crafting the provisions of the bill.

[6] Commission draft report on reform of commercial laws, 2002

[7] There are lecturers at the faculty of Law, Makerere University who have studied the subject, one of them at PHD level. There are other experts in private practice and NGOs who could have provided technical input.

HEP'S CRITIQUE OF THE PROCESS AND THE DRAFT BILL

Under the funding by HAI Africa, coalition for Health promotion and Social Development (HEPS) did a review of the IP Bill and submitted a memorandum of Uganda Law Reform Commission in June 2002. some of the issues HEPS raised are:

(a) The Draft Bill

The bill was not public health sensitive. Under this review, HEPS made proposals on the following provisions:

Compulsory licensing

The draft provision on compulsory licensing required applicants to apply to court. HEPS appreciated the presence of this provision but pointed out that such a procedure would be cumbersome. HEPS proposed that the interest of a country like Uganda should be to have a legal provision that makes it easy to acquire a compulsory license and in the most expedient manner. To this end HPES proposed that an administrative procedure be adopted.

HEPS UGANDA/Access Coalition consultative meeting. Left to Right: Dr. Olive Ssentumbwe-WHO Kampala, Ms. Rosette Mutambi-Coordinator HEPS, Ms. Mebrat Woldetensaie-Coordinator HAI-Africa, Dr. Francis Runumi-Commissioner Ministry of Health.

In addition, HEPS pointed out that the provision demanded unnecessary guarantees from an applicant to satisfactorily work the invention to remedy the deficiency of the products. This is very onerous and may scare away the potential generic manufacturers. In the opinion of HEPS, increased and easy access to medicine is satisfied by any increase in the availability and affordability of medicine and need not be done by a single licensee. Since a compulsory license is non-exclusive, several license may be granted and leave the rules of competition at play and economies of scale for the licensees to determine. In this regard, HEPS proposed that an applicant be granted a compulsory license as long as he satisfies the tribunal that he can produce the products.

> ***"The draft provision stated that, "a compulsory license shall not be granted unless the person requesting for the license (b) offers guarantee satisfactory to the court to work the relevant invention sufficiently to remedy the deficiencies or to satisfy the requirements which give rise to his or her request.***
>
> ***HEPS did not provide alternative wording but stated that the whole provision needed to be redrafted to make it easy for applicants for a compulsory licenses.***

Parallel importation

The draft bill allowed products to be put on the market by the patent owner or with his "express consent".

> ***"The rights under the patent shall not extend to acts in respect of articles which have been put on the market with express consent of the patent owner"***

HEPS argues that a country with no manufacturing capacity would benefit better from a wide interpretation of parallel importation provision. This wide interpretation could only be achieved by avoiding the words "express consent of the owner". The following phrasing was proposed

> "***The right under the patent shall not extent to acts in respect of articles which have been legitimately put on the market in any part of the world".***

HEPS further argued that the spirit of parallel importation at least in terms of increased access to drugs require that the law makes it very easy for a government to import drugs form cheaper sources without much hussle. The requirement for consent is in the interest of the patent owner and not the

consumer. Moreover, TRIPS agreement does not obligate any member country to consider consent when taking a decision to engage in parallel importation. HEPS proposed that the words "express consent of the owner" be deleted and replaced with a provision that allows the government to import any drugs legitimately on the market anywhere in the world.

Bolar provisions

HEPS also found the provision on Bolar exception to be limited in scope and suggested a provision that covers not only scientific research but also processes such as registration and testing for purposes of producing and commercializing the product as soon as the patent expires. The draft phrasing is as follows:

The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research

HEPS' proposed the following alternative:

"The exclusive acts of the patent owner shall not extend to acts done for purposes of research or for the purpose of obtaining regulatory approvals and/or registration for purposes of commercialising the invention after the expiry of the term of the patent".

Doha Declaration

The draft bill also had not catered for developments of the Doha Declaration. HEPS pointed out that achievements such as the extension of transition and provisions for determining of what constitutes an emergency and the competent authority to declare emergency should be included.

(b) Process

In terms of process, HEPS was of the view that the process was rushed given the fact that Uganda as a country had not done independent study of the issues under the global debate from its own perspective in order to generate the right policy options. The TRIPS Agreement offers a grace period to developing countries. HEPS argued that the negotiators of the TRIPS agreement had a reason for granting least developed countries a transitional period of up to 2006, which Uganda should not overlook. HEPS also argued that in spite of the achievements of the Doha declaration and the discussions at the TRIPS Council, a new look at the issues may be necessary. However the Commission and the government seemed poised to go a head with the reform with no further

consultation. HEPS cited the example of pharmaceuticals. Under the Doha Declaration, least developed countries are not obliged to grant pharmaceuticals patents until 2016. On the basis of this exemption, Uganda has the freedom to expressly provide in the IP bill that pharmaceuticals shall not be patented until the expiry of the transitional period. In order to build stakeholders pressure, HEPS organized a coalition comprised of human rights groups and CSOs to steer a campaign for a health sensitive legislation. The coalition held media briefings and stakeholders workshops for journalists on issued regarding patent law reform and its relevance to public health. Consequently a few articles have appeared in local and international media pointing out the need for caution in reforming patent law. [8]

HEPS also argued that civil society organizations should have been consulted in the initial stages of the reform process to enable them undertake studies. HEPS joined other CSOs in agitating for more time to present their their independent views. As it turned out, the bill was not presented to cabinet as scheduled and HEPS was able to present its views. In addition some degree of public interest was stimulated and public health concerns raised.

The unfinished process

At the moment the draft IP bill is not yet submitted to cabinet and it is not indicated when it will be submitted. But the commission has been promising to submit it every end of month since April 2002. Because it is not yet before cabinet, it becomes even more difficult to speculate when it will go to parliament. There are all indications that owing to our intervention, the government pace has subsided.

Although the process seems to be steered by Uganda, it is likely that the US will try to push its interests. But HEPS is also trying to interest the public in the debate and to express its views in respect to the impact of patents on public health. HEPS is also planning a range of activities including technical briefings for members of parliament, media programs on radio, TV, collaboration with Ministry of Health and WHO in Uganda. In the final analysis, we expect the Commission to consider our proposals in the final draft.

Lessons for other countries

The most important lesson for any developing country that seeks to reform its laws is that failure to do independent study and to identify policy objectives

[8] An article appeared in the Herald Tribune Newspaper around March 23 2002. another appeared in a Ugandan Newspaper, The Monitor around the same period.

exposes the country to foreign interests. Consultants may be useful but one can never tell where their interests fall. This uncertainty is even worse where donors hire consultants as part of the project package. Countries need to do independent studies to develop policy alternatives rather than depend on ideas floated by the powerful countries.

The other lesson is that stakeholders should be involved early enough to enable them get to proper grips with issues under debate. In addition, tasks forces or committees appointed to make an input should be selected on the basis of expertise and experience.

Conclusions and Recommendations

While the pharmaceutical industry and some Northern governments are content with patent laws that serve their interest, many agencies, from UN bodies to non-governmental organizations and the independent Commissions on intellectual Property Rights, believe that the potential negative impact of TRIPS on the developing world must be minimized. Their recommendations include:

At International level

- Alternative methods of worldwide sharing of R & D costs should be developed.
- Unilateral pressure on countries to adopt trade, patent or health legislation that is not in public interest and is not legally required should be ended
- Reliable cost data on the development of new drugs should be made public.
- Commitment of funding by the international community, and many different partnerships between governments, multilaterals, non-governmental organizations, research institutions and private companies
- Public involvement to ensure development of new drugs for certain priority health problems.

From a national perspective:

- Ministries of health must work closely with other ministries (trade, justice etc) to formulate and/or revise national patent legislation to ensure that public health needs are fully taken into consideration.

- National legislation should narrow to an absolute minimum the type and scope of pharmaceutical patents.
- Developing countries should ensure that their legislation allows for compulsory licensing
- Proposed national legislations should be subject to extensive scrutiny by policy-makers, the media, non-governmental organizations and other representing patients' needs and rights.
- Least developed countries should delay granting of pharmaceutical patents as long as possible
- Development objectives should be integrated into the promotion of intellectual property rights in developing countries
- There should be policies and commitment by governments to establish funding priorities and national healthcare capacity.

Key question for Journalists and policymakers on intellectual property issues

Drugs and statistics

- In your country, what are the leading causes of illness and death?
- Who pays most for healthcare: the government or individuals?
- What proportion of an individual's income goes to healthcare?
- Is the government supportive of ensuring access to essential drugs for the poorest sectors of society?
- Which drugs are under patent?
- Is there national capacity to manufacture drugs?
- Is thee domestic generic production capacity? If so, which generic alternatives are manufactured?
- What steps has the government taken to ensure supply of patented drugs at affordable prices?
- Are any multinational companies seeking to patent local remedies, or herbs?

WTO and TRIPS

- Is your country a member of the World Trade Organisation or applying for membership?
- If it is a member, when is it required to the TRIPS- compliant?

- Have the implications of TRIPS been fully discussed in national debate involving civil society? If not, why not?
- Does national legislation already comply with TR-IPS or even TRIPS-plus? Are there moves to make it comply earlier than it needs to? If so, who is pushing this?

National legislation and its implementation

- What national legislation had been passed or is under consideration to implement TRIPS?
- How effective is the national or regional patent office?
- How effective is the supply of drugs regulated?
- What is the situation regarding differential pricing?
- What is the situation regarding compulsory licensing?

Annexure A

INSTITUTION/ORGANISATION	NAME OF REPRESENTATIVE
1. Uganda Law Reform Commission	(i) Prof. J.M.N. Kakooza (Chair)
(ii) Jean L.Kyazze,	
	(iii) Apecu Joan,
	(iv) Odoki Philip,
	(v) Akubu Jeroline,
	(vi) Pius. P. Biribonwoha
2. Attorney General's Office-Ministry of Justice	} Ketra Tukuratiire & Rita Bbanga
3. Registrar General's department	
4. Ministry of justice	
5. Ministry of Tourism, trade and Industry	Peter Elimu Eryetu
6. Uganda Law Society	Vincent Emoru
7. Judiciary Commercial court	Ruhinda Ntengye Asaph
8. Uganda Revenue Authority	Mr. Tokoma
9. Uganda Investment Authority	Samuel Kaali
10. Private Sector Foundation Uganda	Nimrod Waniala
11. Law Development Centre	Patrick Mugisha
12. Faculty of Law Makerere University	Ezekiel Tuma
13. Uganda National Council for Science and Technology	Flanklin Muyonjo
14. Inter-University Council of East Africa	Prof. Golola
15. Ministry of Agriculture Animal Industry and Fisheries	
16. Supportive for Private Expansion and Enterprise (SPEED)	Jimmy Muyanja
17. Uganda Manufacturers Association	Sarah Walusimbi & Mary Kusambiza
18. Non Governmental Organisation Representative	Jane Nalunga & Davis Ddamulira
19. Ministry of Foreign Affairs	Ambassador Kangwagye
20. Uganda Broadcaster's Association	Aga Sekalala
21. Uganda Performing Artists Society	James Wasula
22. Uganda Musicians Union	Dick Matovu
23. Coalition for Health & Social Dev't (HEPS-UGANDA)	Patrick Mubangizi
24. Medicines san frontiers	Spring Gombe

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