GAO

Briefing Report to the Honorable
Lloyd M. Bentsen, United States Senate

July 1987

U.S.-JAPAN TRADE

Interim Report on Sector-Selective Agreements

GAO/NSIAD-87-186BR

GAO

United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

B-227630

July 10, 1987

The Honorable Lloyd M. Bentsen
United States Senate

Dear Senator Bentsen:

On February 25, 1987, you requested that we evaluate U.S. initiatives designed to further open Japanese markets and reduce nontariff barriers, thereby increasing the potential for U.S. exports to Japan. Specifically, you asked us to assess the results of the Market-Oriented Sector-Selective (MOSS) talks, which currently cover five industrial sectors: telecommunications, pharmaceuticals/medical equipment, electronics, forestry products, and auto parts. You also requested that we first assess the U.S.-Japan Semiconductor Arrangement, which had been negotiated as an adjunct to the electronics-MOSS talks. On April 15, 1987, we delivered a briefing report entitled International Trade: Observations on the U.S.-Japan Semiconductor Arrangement, (GAO/NSIAD-87-134BR).

As arranged with your representative, we are providing this interim briefing report covering two of the five MOSS sectors--telecommunications and pharmaceuticals/medical equipment. Our overall assessment of the results of the MOSS talks, including all five sectors, is continuing and we will report on that work at a later date.

The telecommunications and pharmaceuticals/medical equipment sectors were very appropriate for sector-specific negotiations under the MOSS framework. The U.S. industries in each sector were internationally competitive and stood to gain a sizable market share in Japan if both formal and informal trade barriers were eliminated. Prior negotiations had taken place between the United States and Japan on these sectors, so certain primary agenda issues were already largely established. But perhaps most importantly, a coincidence of interests existed between Japanese and U.S. objectives--both U.S. and Japanese industry and government officials generally recognized that liberalization of these Japanese markets was needed. These factors, among others, led to the successful achievement of many of the MOSS objectives and substantial bilateral agreements in each sector.

Most U.S. industry and government officials we contacted were generally supportive of the MOSS process and were pleased with the agreements reached. However, industry representatives generally were unable to attribute measurable increases in exports or market share directly to the MOSS process and stressed the need for continued U.S. pressure to ensure that the agreements achieved thus far yield real market opportunities. Most of these representatives agree that it is too soon to judge the full impact of these MOSS agreements, since reliable data is not currently available to develop an accurate, and quantifiable, determination of success.

Appendices I through III provide more detail regarding the MOSS process and preliminary information on the results of the specific sectoral negotiations involving telecommunications and pharmaceuticals/medical equipment, outstanding issues, and industry observations on the actual outcome of the agreements reached.

We discussed this briefing report with Commerce and Treasury Department officials having specific responsibility for the two MOSS sectors discussed, and we have made modifications to reflect their comments. As requested, we did not obtain formal agency comments. We are sending this report to other interested parties. If you have questions on the information provided please contact me on (202) 275-4812.

Sincerely yours,

Allan I. Mendelowitz

Allan I. Mendelowitz
Senior Associate Director

Contents

Abbreviations

AT&T	American Telephone and Telegraph
GAO	General Accounting Office
GATT	General Agreement on Tariffs and Trade
JATE	Japan Approvals Institute for Telecommunications Equipment
MHW	Ministry of Health and Welfare
MOSS	Market-Oriented Sector-Selective
MPT	Ministry of Posts and Telecommunications
NTT	Nippon Telegraph and Telephone
PMA	Pharmaceutical Manufacturers' Association

APPENDIX I

THE U.S.-JAPAN MARKET-ORIENTED SECTOR-SELECTIVE TALKS

The Market-Oriented Sector-Selective (MOSS) talks were initiated as a result of a meeting between Japanese Prime Minister Nakasone and President Reagan on January 2, 1985, at which time they discussed the MOSS format as a means to address the difficult issue of market access in Japan. Frustration regarding trade relations with Japan had reached a high level in the United States. Concern had risen with the increase in the U.S. trade deficit, and complaints of Japanese unfair trade barriers proliferated. The MOSS talks concept would allow negotiation of these issues on a sectoral rather than a case-by-case basis and could, therefore, address all trade barriers within a selected sector.

The MOSS negotiations were patterned on the 1984 U.S.-Japan Yen-Dollar agreement, which was a successful approach contributing to the liberalization of Japanese financial markets.[1] Likewise, the MOSS talks were intended to create overall trade liberalization.

The MOSS bilateral negotiations began in late January 1985. They were structured to be held by high level officials--Japanese vice ministers and U.S. under secretaries being the key negotiators--to highlight the importance of these bilateral talks and to ensure that the negotiators would have the authority to reach an agreement on the very complex set of issues characterizing each sector. Further, this negotiating approach proved unique in that there was no bilateral "bargaining" with each side making concessions--rather, the United States was negotiating for unilateral change in Japan's trading practices.

Four sectors were initially chosen--telecommunications, electronics, pharmaceuticals/medical equipment, and forestry products.[2] These sector selections were generally based on the following criteria:

- A history of wide-ranging trade complaints, of either formal or informal trade barriers, had to exist.
- The U.S. industry had to be internationally competitive.
- The products under discussion had to constitute a sector.
- U.S. market share in Japan had to be low.
- The potential for increased U.S. sales had to exist.
- The U.S. industry had to be interested in the talks and willing to provide backup information.

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[1]For a detailed analysis of the Yen/Dollar Agreement see our report International Finance: Implementation of the Yen/Dollar Agreement (GAO/NSIAD-86-107, June 3, 1986).

[2]Automobile parts was added as a fifth sector in the MOSS talks in 1986.

- There had to be good prospects for near-term, observable results (i.e., within 3 to 5 years).

Negotiating objectives were established through an interagency process, although each sector had a specified lead agency--the Department of Commerce was responsible for telecommunications, the Office of the U.S. Trade Representative for electronics, the Department of Agriculture for forestry products, and the Department of Treasury for pharmaceuticals and medical equipment--with responsibility for general oversight of the entire process given to the Department of State. Other government agencies and industry associations participated, as needed, to provide technical advice.

The telecommunications and pharmaceuticals/medical equipment sectors are the two sectors generally credited with achieving the greatest success from the MOSS talks approach. Negotiations in each of these sectors yielded a series of agreements on specific issues.[3] Both sectors represented large potential markets for U.S. exports. Japanese markets in both sectors were also generally considered closed, over-regulated, and in need of liberalization. Based on prior bilateral discussions, specific changes had already been identified as necessary to remove excessive government regulation and to create market openness equivalent to that found in the United States. Indeed, a major factor in the successful negotiations in both cases was the recognition--by a number of U.S. and Japanese industry and government interests--that liberalization of these Japanese markets was necessary. This coincidence of interests between the U.S. and Japanese objectives led to the perception of gain on each side and exerted political pressure from both countries towards changing Japanese practices.

Objectives, scope, and methodology

Our objectives were to delineate the issues involved in the MOSS talks on telecommunications and pharmaceuticals/medical equipment, and describe the results of the agreements reached thus far in these sectors. We developed information on the MOSS process, the results of the specific sectoral negotiations, monitoring efforts regarding outstanding issues, and industry observations on the results obtained from the MOSS process. Our information is largely based on interviews with the principal associations representing these industries, specific U.S. industry representatives, as well as the primary U.S. government representatives involved in the actual negotiations. We contacted representatives from the American Electronics Association, the Electronic Industries Association, the Health Industry Manufacturers' Association, and the Pharmaceutical Manufacturers' Association, and interviewed agency officials from the Office of the U.S. Trade Representative, and the Departments of State, Commerce, and the Treasury.

The information in this interim report will be used in our overall assessment of, and future report on, all five sectors covered by the MOSS talks.

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[3]Reports summarizing the bilateral agreements reached in these two sectors were released in 1986.

THE TELECOMMUNICATIONS SECTOR

Prior to the MOSS talks, the United States and Japan signed an important bilateral telecommunications agreement negotiated as an adjunct to the General Agreement on Tariffs and Trade (GATT) Government Procurement Code. As part of this agreement, which became effective in 1981, Nippon Telegraph and Telephone (NTT), then a government-owned monopoly, agreed to allow foreign telecommunications equipment suppliers to compete for its procurements. However, in 1985 the need arose for the United States to negotiate further telecommunications agreements, since legislation had just been passed by the Japanese Diet on the privatization of NTT. This legislation provided an opportunity for the United States to negotiate major changes in Japanese telecommunications regulations that could greatly increase the opportunity for sales by foreign companies and also guard against the possibility that privatization would itself develop new trade barriers or undo the progress achieved in prior agreements.

Pressure to liberalize Japan's telecommunications market came from both domestic and foreign sources. Foreign firms wanted to eliminate barriers to market access to Japan's growing telecommunications market, which is the second largest in the world, while Japan wanted to gain access to foreign technology. The Ministry of Posts and Telecommunications (MPT) believed that the advancement of telecommunications would play an important role in changing Japan's industrial structure and expanding the domestic economy. The U.S. telecommunications industry felt it had a competitive advantage in many products, especially in enhanced services and high technology equipment, which could be translated into a large market share if it had fairer access. Further, the U.S. government was eager to increase exports to reduce the billion-dollar trade deficit with Japan in this sector.

The disparity between U.S. and Japanese market access was a major concern. The U.S. telecommunications market had been changed dramatically by the AT&T divestiture, which led to extensive U.S. market opportunities for foreign companies. With the pending privatization of NTT, a similar opportunity was presented to open the Japanese telecommunications market to foreign competition. Within Japan, there was a growing recognition of the need to modernize the telecommunications regulatory structure, and the U.S. government asserted that the lack of transparency of Japanese regulations and standards pertaining to telecommunications created essentially invisible trade barriers. The timing and trade environment was therefore ripe for these MOSS negotiations.

The telecommunications talks were conducted in two phases. Phase one focused on telephone communications, or wired equipment and services that included basic telephone and enhanced or value-added services. Phase two focused on wireless, or radio, services and equipment that involved radio frequency allocation, pagers, and cellular phones.

Phase one

Beginning in January 1985, phase one negotiations centered on the issues of standards,

certification, and testing of terminal equipment and value-added network services. The U.S. government sought greater transparency in the Japanese rule-making and standard-setting process, a reduction in the actual number of standards, and the liberalization of the market for terminal equipment by adopting the U.S. standard of "no harm to network." This standard, used successfully in the United States for 10 years, allows any component or part to be used in a telecommunications system as long as it will not damage that system. Regarding the certification and approval process, the United States sought an impartial approval board (that would advise MPT) as well as transparency of the approval process. In addition, the United States wanted Japan to accept foreign (U.S.) test data.

The negotiations for phase one concluded on April 2, 1985, when the United States and Japan signed an accord on wired telecommunications issues that achieved most of the U.S. objectives. One of the accord's provisions led to the opening of Japan to foreign-operated, value-added telecommunication services. The standards issue had been resolved by greatly increasing the transparency of the drafting procedures and allowing foreign manufacturers to comment. Further, there was a dramatic reduction in the number of standards (from 53 to 21), with the remaining standards to be reviewed and possibly eliminated. Most important, the standard of "no harm to network" was implemented which made Japan the only country, besides the United States, to have such a liberal standard.

Other major MOSS accomplishments included simplifying the application and approval procedures for terminal equipment. The Japan Approvals Institute for Telecommunications Equipment (JATE) was set up as an independent agency to determine conformity with technical standards. As in the United States, Japan simplified its approval process which became a matter of paper examination and approval, generally without any additional testing requirements. Further, while foreign representatives still cannot be members of the Telecommunications Advisory Council, a Japanese employee of a Japanese subsidiary of a foreign firm now can.

Phase two

Phase two of the MOSS telecommunications talks, which began mid-1985, focused on radio telecommunications. The issues for wireless communications were generally similar to the wired sector, because Japanese standards and regulations for this sector were also considered outdated and tended to limit access to this market by foreign firms. Therefore, U.S. negotiators sought to simplify Japanese licensing and approval procedures, to broaden the opportunities for foreign companies to provide third-party services, and to promote acceptance of foreign test data. Additional issues involved the allocation of radio frequencies and the government procurement of radio equipment and satellites.

During phase two, no action forcing event occurred, such as impending legislation, to help achieve quick progress in this set of negotiations. However, by November 1985 Japan had moved closer to U.S. requests for self-certification, offered greater transparency in administration of rules regarding radio transmission (reducing the

number of standards from 10 to 1 for radio receivers and reviewing those for cellular telephones), and established the Radio Inspection Approval Institute which issues individual approvals for radio equipment. With the liberalization of the telecommunications sector, Japan permits the use and purchase of U.S. satellites by private firms but still prohibits government procurement. Phase two concluded in January 1986, and in April of that year the Japanese government amended the Radio Wave Law to allow foreign access to radio station licenses for cellular telephones. Further, foreign companies will be able to provide a variety of new and existing radio services in Japan on a 100-percent equity basis. In May of 1987, several further amendments to the Radio Wave Law were passed by the Diet, simplifying procedures for licensing radio stations. However, differences on standards and allocation of radio frequencies still remain.

Monitoring effort and continuing issues

A MOSS Telecommunications Oversight Committee was created to include representatives from the U.S. Embassy in Tokyo and the MPT and has met seven times since September 1986. U.S. industry representatives also took part in these meetings. The Committee is not meant to serve as a problem-solving group, but to identify problems, monitor implementation, and develop further information. One of the primary objectives of the Committee was to develop an information exchange process that would provide regular updating of MPT's administrative, regulatory, and policy changes. Prior to the establishment of this Committee, U.S. firms were advised infrequently, if at all, of such changes. This information exchange process has been credited with developing a dramatic increase in transparency of MPT procedures.

The telecommunications issues that remain to be resolved are generally in the wireless communications market. Since the government of Japan did not originally plan legislative changes in this sector, negotiations to develop market liberalization equivalent to that achieved for the wired telecommunications sector proved more difficult. Although access to the Japanese telecommunications market has been increased by the MOSS agreements and changes in Japanese law--for example, allowing greater foreign participation in telephone and radio communications--it remains uncertain how this will translate into actual sales of telecommunications services and equipment.

Specifically, Japan's cellular telephone market has been an area of concern since allegations arose about discrimination against foreign firms. MPT had responded to competition from two competing corporations by parcelling out service districts--effectively carving up the Japanese cellular communications market. One Japanese corporation, utilizing an NTT-developed system, was granted the Tokyo to Nagoya metropolitan area, whereas the other corporation, operating in partnership with a U.S. firm and using a U.S.-developed system, received a less densely populated service area. However, in response to U.S. government remonstrations, MPT agreed to assign additional districts to the latter (but still not Tokyo or Nagoya) and also to ensure access to the nationwide NTT ground station network.

Impact of agreement and industries' views

Both phases of the telecommunications MOSS talks are generally considered, by both U.S. government and industry officials, to have achieved a great deal of success since a primary U.S. objective of bringing Japanese standards into line with those of the United States was largely accomplished.

In general, telecommunications representatives maintain that the majority of competitive U.S. companies in the Japanese wired telecommunications marketplace are satisfied with their access to the telecommunications services market, the customer premises equipment market, and the common carrier market. Transparency and access have also improved in radio communications. The American Electronics Association estimates that more than $300 million in sales for U.S. companies was realized in the past 2 years that could not have been realized had the MOSS talks not taken place. However, due to the recent conclusion of the talks, along with difficulties in determining actual export data, both U.S. government and industry officials believe that it is too early to judge the full impact of these agreements. In addition, the recent appreciation of the yen relative to the dollar should also have influenced sales data, making it difficult to estimate the effect of the MOSS agreements alone on U.S. export sales.

Many officials recognize that the timing of these talks had a lot to do with the success achieved. For example, one U.S. manufacturer felt that through the MOSS agreements Japan got "...credit for something they were planning to do anyway". Nonetheless, some industry representatives claim surprise at how much change, at least on paper, was brought about by the MOSS negotiations. One industry representative told us that, although it is too soon to judge the long-range impact of the MOSS talks, overall "the industry was thrilled" with the outcome. Due to the increased access to the Japanese marketplace, U.S. firms can feel a new "comfort level" regarding investing resources necessary to compete in Japan because at least now they feel like they have "a fair shot."

Concern still exists, however, regarding the U.S. telecommunications industry's ability to develop a large increase in market share in Japan for telecommunications equipment, as well as services, especially over the long term. Industry and government officials believe structural changes within Japan are still needed before discrimination against foreign companies is eliminated. The amount of foreign participation which will actually be allowed in Japan is still at issue. Concern is especially strong when one-time procurements or long-term contracts are granted to domestic versus foreign suppliers. Some industry representatives believe that the Japanese will allow U.S. companies to be only marginal players in certain markets, and then only if U.S. political pressure is continually brought to bear.

PHARMACEUTICAL/MEDICAL EQUIPMENT SECTOR

Prior to the initiation of the MOSS talks in 1985, the government of Japan and the United States had been involved in negotiations to open the Japanese health care market. As a leading force in international pharmaceutical markets, the highly competitive U.S. industry hoped to gain greater access to the $19 billion Japanese pharmaceutical market. Medical equipment producers were primarily interested in changes to the many bureaucratic requirements of the Japanese system of approvals. The United States Trade Representative and the Department of Commerce had already reviewed Japanese regulations and identified major issues. The U.S. government was therefore able to develop clear objectives for the ensuing MOSS talks.

The MOSS talks in the pharmaceuticals/medical equipment sector concentrated on issues related to testing and test data, the approval and licensing processes themselves, the National Health Insurance reimbursement system, and the transparency of procedures.

Especially significant reforms negotiated in the MOSS talks included changes in acceptance of foreign clinical test data, improvements to its system of approvals and reimbursement system, and changes in the transparency of Japanese regulations.

Testing and test data

Prior to the MOSS discussions, Japan required all firms to supply test data generated by clinical trials in Japan involving resident Japanese citizens. This requirement led to costly delays for U.S. and other producers, who had to duplicate testing already performed in other parts of the world, even when differences between testing populations did not have any bearing on clinical results. Effective July 31, 1985, Japan agreed to accept foreign clinical test data for pharmaceuticals except for three categories in which immunological and ethnic differences exist between Japanese and foreigners (comparative clinical trials; dose finding tests; and absorption, distribution, metabolism, and excretion tests). Japan will accept foreign clinical data with respect to

- -- in-vitro diagnostic reagents,[1] except for those with new parameters (measuring a new substance as a diagnostic indicator) and
- -- medical devices except implantables and those devices affecting organic adaptability.

Both the United States and Japan agreed on significant improvements in Japan's regulatory testing requirements for stability and sterility tests and for biological products, including blood products.

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[1]Products used in outside-the-body tests, such as rabbit serum used for urine pregnancy tests.

Approval and licensing processes

The Ministry of Health and Welfare (MHW) requires two separate approvals for firms and their Japanese representatives to participate in Japan's health care system. First, a firm (whether domestic or foreign) must obtain from MHW a manufacturing or import approval of the pharmaceutical product or medical device. Second, the Japanese manufacturer or importer must obtain a license to manufacture or import the approved product. Prior to the MOSS talks, the regulatory system did not provide for standard processing times for new approvals and licenses and did not allow for an orderly transfer of approvals and licenses between business entities. In addition, it required formal reapproval of all products for relatively straightforward transactions such as relocation of facilities.

Japan agreed to make significant changes to its regulatory requirements for approvals (which took effect between July 31, 1985, and October 1, 1985). These changes included establishing "time clock" (standard processing) procedures analogous to those used by the Food and Drug Administration in the United States; establishing procedures for handling the transfer of approvals to recognize changes in commercial relationships; simplifying the procedures for routine business transactions (such as a change of location of facilities); and creating a separate, distinctive approval review process with simplified documentation requirements for in-vitro diagnostic reagents.

The approval system also did not have fully consolidated application, approval, and pricing procedures to allow combinations of previously approved drugs and devices to be packaged together in medical kits. MHW has devised approval procedures, effective April 1, 1986, and pricing procedures for medical kits, which can now be priced appropriately under the regulations governing the insurance reimbursement system.

The National Health Insurance Reimbursement System

After securing the approvals for the drug or medical device and for the manufacture or import, firms apply for a price listing for the product under the National Health Insurance reimbursement system, which covers almost 100 percent of the Japanese population. U.S. producers were concerned about the irregular and infrequent listing of reimbursement rates as well as the criteria used to set reimbursement prices. As a result of the MOSS talks, Japan agreed to provide quarterly price listings for all new drugs and many medical devices. Thus, potential delays between approval and price listing for these products will be no more than 90 days, and MHW committed itself in principle to delays of no more than 60 days in limited circumstances. Also, innovative in-vitro diagnostics can be introduced into the reimbursement system within 6 months after their approvals, effective April 1, 1986.

Transparency

The government of Japan agreed that MHW and its advisory body, the Central Pharmaceutical Affairs Council, will hold educational meetings on its procedures. The Social Insurance Medical Affairs Council, the body within MHW that makes reimbursement decisions, will also provide both foreign and domestic firms opportunities to present their views on general reimbursement policy decisions as well as particular

pricing decisions. The formulas used for calculating new drug prices and for revising drug tariff standards will be made public. In accordance with the MOSS agreements, MHW established and announced by mid-1986 its general rules for setting and revising prices of medical devices and in-vitro diagnostics.

Unresolved issues and monitoring

Although the United States and Japan developed general language to deal with the acceptance of foreign clinical test data and improvement to the reimbursement process, they left unspecified how Japan will implement these approaches. They were unable to resolve the issue of vitamin regulation and agreed to hold further discussions. They also did not fully resolve the issue of unfriendly transfers of approvals, i.e., transfers in which the Japanese representative of a U.S. firm and the U.S. firm disagree about which one should hold the approval. Japan and the United States committed themselves to "finding practical solutions to legitimate business problems" in this area.

The United States and Japan signed the joint report specifying the agreements reached during the MOSS talks on January 9, 1986. They agreed that follow-up meetings would be important for implementing the agreed measures and thus scheduled regular follow-up meetings during 1986 and on schedules to be decided in later years, as necessary. Several meetings have been held since the agreements were reached.

Impact of agreements and industries' views

Both the pharmaceutical and medical equipment industries report satisfaction with the MOSS agreements. The pharmaceutical industry benefited generally from the more open regulatory process negotiated in the MOSS talks, and it remains cautiously optimistic, noting that the long-range impact of the agreements is still unknown due to the lengthy product cycle for pharmaceuticals (8-10 years). The degree of satisfaction reported within the medical equipment industry varied depending on the type of products produced and the extent to which the changes in the regulations affected the marketing of those products. Firms producing innovative products experience difficulties because these products are slow to gain general acceptance by the Japanese medical community and thus are also slow to gain acceptance into the National Health Insurance reimbursement system.

Although the associations and firms we contacted were pleased with the new acceptance of foreign clinical test data by Japan, the Pharmaceutical Manufacturers' Association (PMA) observed that "there is something to be gained by doing testing in Japan." One government representative pointed out that testing in Japan helps new products gain market exposure. The associations shared one area of dissatisfaction; both associations noted that the length of time for formal monitoring is too short to evaluate the actual impact of the agreements due to the relatively long product cycles of products in this sector. PMA points out that only one-eighth of a product cycle has elapsed since the medical MOSS talks.

Sales data may not accurately measure the effectiveness of the MOSS talks due to the weakening of the dollar since February 1985. Although drug and medical equipment sales measured in dollars have increased since the MOSS talks, changing foreign

exchange rates may account for part of this. Both PMA and the Health Industry Manufacturers' Association suggest that the best measure of success is the decline in the number of complaints they have received since the conclusion of the medical MOSS talks.

One medical equipment supplier credits the dramatic increase in his firm's approvals to the separate process for medical devices established by the MOSS talks. This U.S. firm's Japanese affiliate reports that MHW has been reviewing and approving product submissions within the agreed-to time frame of 6 months and notes that, prior to the MOSS talks, this time frame was 2 to 2-1/2 years.

One indirect result of the MOSS talks was the cooperative relationship that emerged between the pharmaceutical associations in the United States and Japan. This occurred partly because the two associations found that they had mutual concerns with the Japanese regulatory system and, more specifically, with the treatment of patent term restoration.[2] PMA credits the MOSS talks with both the new working relationship between the associations and the current legislation before the Diet regarding a 5-year patent restoration time period.

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[2]Patent term restoration refers to the extension of the patent protection period to compensate the firm for time lost due to the lengthy regulatory approval process.

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