

**The 10 burning questions  
on the Government Use of Patents  
on the four anti-cancer drugs  
in Thailand**

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And  
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## **The 10 burning questions on the Government Use of Patents on the four anti-cancer drugs in Thailand**

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## **Question 1: What is the rationale for the implementation of the Government Use of Patents on the four anti-cancer drugs?**

Cancer has been one of the top killers among Thai people for over a decade. It is the cause of more than 30,000 deaths annually in Thailand, with more than 100,000 new cases reported each year. Cancer is no less serious than HIV/AIDS. The leading types of cancer in Thailand are lung and breast cancer. There are many new “chemotherapeutic and targeted therapies” that have been developed in the last decade. Most of these new anti-cancer drugs are patented, costly, and cannot be accessed by the poor, nor by many members of the middle class. Many of these new drugs are not included in the National List of Essential Drugs (NLED) due to their high price, nor are they covered by the National Health Insurance system. Patients who try to pay their expenses out of pocket will soon face catastrophic illnesses and will bankrupt their family, or will have to stop taking the drugs due to financial constraint. These problems prompted the National Health Security Board to find ways to provide universal access to essential medicines without any financial barrier.

The implementation of the Government Use of Patents on the four anti-cancer drugs was based on the advice of the Subcommittee on Selecting Essential Drugs with Access Problems under the National Health Insurance schemes and was confirmed by the Committee to Support the Implementation of the Government Use of Patents. The only reason for the implementation of the Government Use of Patents is to *allow universal access to essential medicines by all the beneficiaries of the National Health Security System, which are all publicly financed schemes. This is the goal of the previous as well the new Thai Constitution of 2005, and the National Health Security Act of 2002.* The details of the rationale are as follows (information before negotiation by the Negotiation Committee):

1. The drug Docetaxel (trade name Taxotere) is used to combat lung and breast cancer. The price of an 80 mg. injection for this patented medicine is 25,000 Baht, while the generic equivalent costs only 4,000 Baht, representing a price differential of more than 6 times the amount for a patented medicine than its generic equivalent.

2. The drug Letrozole (trade name Femara) is used to combat breast cancer. The price of one tablet of 2.5 mg. of the patented drug is 230 Baht, while the price of the generics are 6-7 Baht, representing a price differential of 30 times the amount for a patented medicine than its generic equivalent.

3. The drug Erlotinib (trade name Tarceva) is used against lung cancer. The price of one tablet of 150 mg. of the patented drug is 2,750 Baht, while the generic costs only 735 Baht, representing a price differential of more than 4 times the amount for a patented medicine than its generic equivalent.

4. The drug Imatinib (trade name Glivec) is used to combat Chronic Myeloid Leukemia and Gastrointestinal Stromal Tumor (GIST). The price of a 100 mg. tablet of the originator brand costs 917 Baht, while the generic version costs only 50-70 Baht, representing a price differential of almost 20 times the amount for a patented medicine than its generic equivalent.

In conclusion, these four essential anti-cancer drugs can be made available at prices ranging from 4 to more than 30 times lower than the patented products. These lower prices would be affordable to the National Health Insurance Schemes, which would provide the drugs to all who need them. This will further prevent untimely death, as well as catastrophic illnesses, among Thai people.

The Subcommittee on Selecting the Essential Drugs with Access Problems under the National Health Insurance schemes thus proposed a note (annex 1) to the Public Health Minister on September 25, 2007 to implement appropriate measures to increase access to these drugs. The minister then requested the opinion of the Committee to Support the Implementation of the Government Use of Patents. The committee met on October 2, 2007 and proposed the implementation of the Government Use of Patents on the four anti-cancer drugs, requesting that the Government Pharmaceutical Organization obtain good quality generics, and also asking the Food and Drug Administration to persuade the generic drug companies to register the four anti-cancer drugs (the Thai FDA has since issued a letter in keeping with the request – annex 2). The committee chair submitted a note to the Public Health Minister in keeping with the committee resolution of October 19, 2007 (annex 3). In spite of the fact that the Minister can immediately endorse the implementation of the Government Use of Patents on the four drugs, he has requested that the Committee to Negotiate for the Price of Essential Patented Drugs move on with the negotiation. The more than twelve rounds of negotiation went on for more than two months, with limited progress, which led to the final decision to implement the Government Use of Patents on the four drugs.

**Question 2: Has there been any negotiation with the patent-owners before deciding to implement the Government Use of Patents on the four anti-cancer drugs?**

It should be noted that, according to Article 31(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights under the WTO, and Article 51 of the Thai Patent Act, in the case of public, non-commercial use, any ministry, bureau, or department can implement the government use of a patent without the requirement to negotiate with the patent-owner. This has been confirmed by paragraphs 5(b) and (c) of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, which gives WTO members the right to determine under which condition to implement the government use of a patent.

Nevertheless, to allow patent-owners the opportunity to offer appropriate proposals to promote universal access to these four essential anti-cancer drugs, the Public Health Minister decided to request that the Committee to Negotiate for the Price of Essential Patented Drugs enter into discussions with the patent-owners, beginning in mid-October, 2007. Some significant progress has been achieved after more than two months of more than 12 rounds of serious negotiation, including:

**1. Docetexel.** The patent-owner revised its offer two to three times, and the last offer might have brought the price down to around one-third of the original price. However, there were some unpractical conditions for the proposal. For example, the patent-owner proposed to pay for the fourth to sixth round of treatments, with the government paying for the first three to four rounds. This is difficult to implement for each patient, and there is no way to know how much the price can be reduced. The committee has requested that the patent-owner come up with a net reduced price of the drug. The final proposal from the company came on December 20, 2007, with a proposed donation of twice the amount purchased. However, the agreement included the conditions that the drug had to be put into the National List of Essential Drugs and there was to be a minimum amount of annual purchase. Although this proposal may have allowed a price reduction down to one-third of the original price, this is still much higher than the price of generics. The final offer from the generic company to the Government Pharmaceutical Organization of Thailand on February 5, 2007 was 4.7 percent of the original product's price.

**2. Letrozole.** The company provided several proposals with some donation of drugs based on amount of purchase. The last proposal came on December 17, 2007, when it was proposed that the patent-owner would donate an equal amount of drugs purchased, with the condition that purchases had to

total at least 60,000 boxes per year. Nevertheless, the Committee found that the price proposed was still higher than the price that the National Cancer Institute receives, and was still much higher than generic prices.

**3. Erlotinib.** The company only agreed to attend negotiations once out of five invitations. However, the patent-owner proposed on December 21, 2007 to reduce the price to 30 percent, with the condition that the drug had to be put into the National List of Essential Drugs and made reimbursable by all schemes of National Public Health Insurance.

**4. Imatinib.** The initial offer was that the patent-owner would pay for the last 9 months and the government pay for the first three months in a year. The patent-owner would also abolish the Glivec International Patient Access Program (GIPAP) in Thailand. This was not accepted by the Committee. The second proposal was that the patent-owner would allow all patients under the Universal Health Insurance Scheme (the Gold Card Scheme) to apply for assistance under the GIPAP, under the condition that the patient is uninsured and that their household annual income does not exceed a certain level. The level of household income as reported by one oncologist was three times the Gross Domestic Product per capita (or around 300,000 Baht). This condition would have put around 10 million people out of the GIPAP system, which is not acceptable.

In summary, the negotiations have not been successful to the point of fulfilling the conditions that allow National Health Insurance Schemes to provide universal access to these four anti-cancer drugs without undue financial burden. Furthermore, the administrative burdens from the conditions proposed by the patent-owners are also very problematic.

The chairman of the Committee to Support the Implementation of the Government Use of Patents further proposed that the Public Health Minister sign the four Notifications of the Government Use of Patents on the four anti-cancer drugs on December 28, 2007 (annex 4). *The Public Health Minister signed the 4 notifications (annex 5-8) on January 4, 2007. However, to allow for the last chance of negotiation, the minister has decided to defer the implementation of the notifications and request the Negotiation Committee to move forward for further negotiation. The results of this final negotiation are as follows:*

1. Novartis proposed on January 18 and confirmed on January 23, 2008, to allow all patients under the universal health insurance scheme, whose household income is less than 1.7 million Baht per year and need 400 mg. of Imatinib per day, or whose income is less than 2.2 million Baht per year and

need 600 mg. of Imatinib per day, to have free access to Imatinib, if indicated by the attending physicians (annex 9). This condition essentially put all the patients under the universal health coverage scheme into the GIPAP system. So there is no further need to implement the Government Use of Patents on this drug. However, to ensure continuity and sustainability of this commitment from Novartis, a conditional Government Use of Patent was proposed. A new draft of the Ministerial Notification to implement the Government Use of Patent on Imatinib on the condition that the GIPAP fails or is terminated was proposed to the Minister.

2. The other three drugs did not propose any new offer, while the generic drug companies proposed further price reduction. Thus, the committee proposed that the minister endorse the implementation of the notifications signed on January 4, 2008.

More details appear in the note from the Chairman of the committee to the Public Health Minister on January 25, 2008 (annex 10). *The Public Health Minister endorsed the proposal to implement the previously signed notifications, except for Imatinib, and also signed a new notification on the conditional Government Use of Patent on Imatinib (annex 11).*

It is thus very clear that, in spite of the fact that the international and Thai legal frameworks do not require prior negotiation, the Thai Ministry of Public Health has tried its best to move in the constructive direction of negotiating with patent-holders. The success in the case of Imatinib is a good example.

Furthermore, even after the notification has been signed, the Ministry still goes on to negotiate with the patent-holders. If any patent-holder can provide the drugs at a price within 5 percent of their generic competitors, the Ministry will buy from the patent-holders, in spite of the higher price. This 5 percent is meant to reward the loyalty of the patent-holders, and has been used also in the previous three Government Use of Patents. This 5 percent credit point system will be implemented only when the negotiation fails and the ministry has to sign an official notification.

**Question 3: Why did the health minister make the decision during the tenure of the interim government? Could he have waited for the new minister to make the decision?**

From the detailed information in questions 1 and 2 above, it is clear that the process to decide upon the Government Use of Patents on the four anti-cancer drugs started in September 2007. However, the public health minister wanted to create a constructive environment and partnership with the patent-holders, and tried to avoid the implementation on the Government Use of Patents. This is evidenced by the extensive and intensive negotiations conducted by the Ministry resulting in the success in the case of Imatinib. So this is not a new policy or movement. It is, rather, the continued implementation of the established policy of universal access to essential drugs.

The issue of Government Use of Patents is a complex one. It will take much more time for the new public health minister to understand and make the decision. The patients have been waiting since October 2007 for their access to these drugs. If the decision can only be made by the entry of the new government, the patients will have to continue to wait without the hope of access to these drugs.

**Question 4: What are the reasons for the Health Minister's recent visit to India? Has there been any agreement with any Indian generic drug company on the procurement of the generic version of the patented drugs that may be considered as conflict of interest?**

To ensure that generic drugs imported from India are of high quality, the Public Health Minister (Dr. Mongkol Na Songkhla) has visited the Indian drug manufacturers twice.

The first visit was December 15 to 18, 2007. This was to visit the factories of Emcure Pharmaceuticals, Hetero Drugs, Dr. Reddy Laboratories, Netco Pharma, and the Serum Institute of India.

The second trip was on January 8 to 12, 2008. This was to visit the Dabur Company, which produces anti-cancer drugs.

There have been no agreements or Memoranda of Understanding (MOU) signed with any of the Indian drug firms during the two visits. The cost of travel was also paid by the Ministry's and the Government Pharmaceutical Organization's budgets, not by any of the drug companies.

The Minister and the technical team were highly impressed by the high quality standard of the Indian drug factories, and also learned that some of these companies have registered their drugs with the U.S. FDA.

The procurement of generic drugs under the Government Use of Patents is governed by the Government Pharmaceutical Organization procurement rules and regulations. It has to go through a transparent system of open bidding, in which the Public Health Minister has no role or involvement at any step, and there has not been any conflict of interest.

### **Question 5: Is it true that Thailand plans to implement the Government Use of Patents systematically on all patented drugs?**

Since 1992, when Thailand revised its Patent Act to include product patents due to the pressures from the USTR, it is estimated that there have been more than 200 patented drugs registered with the Department of Intellectual Property in the Ministry of Commerce. It is very difficult to know exactly how many patented drugs exist, as the patents are approved in the Thai language and the search is next to impossible. Nevertheless, only seven drugs have been considered for the implementation of Government Use of Patents. This is less than five percent of the total patented drugs. This is clear evidence that the Thai Public Health Ministry implements the Government Use of patents only when truly necessary, not on a routine basis. The decision has to go through the three participatory mechanisms, or committee/subcommittee. This is the strategy to create a transparent and participatory process, and also to allow for negotiation with the patent-holders based on a constructive approach. This may retard the access to essential drugs of the Thai people to a certain extent, but it allows for peaceful solutions.

The three mechanisms that are established to consider each step of the implementation of Government Use of Patents are to ensure transparency, participation, and to generate systematic and constructive approaches. This is to avoid criticism that over processes being ‘unilateral’, ‘non-participatory’, and ‘non-transparent’, ‘non-prudent’, and ‘overused’.

Furthermore, the Ministry of Public Health has also appointed a joint committee between the Ministry and the industries, i.e. Prema, to provide recommendations for the sustainable development of the healthcare system. This is meant to be a prospective and constructive forum for participatory discussion. The committee has agreed on the three objectives:

1. Improvement of the access to essential medicines for low-income people.
2. Reduction of the country’s neglected health problems.
3. Strengthening the national health system’s development capacity.

Further decisions on which other drugs are in the pipeline for possible implementation of the Government Use of Patents depends on the consideration of the Subcommittee, and will be further dealt with by the other two committees. There are two main criteria for their consideration, i.e.:

1. Drugs and medical supplies within the National List of Essential Drugs, or that are necessary to solve public health problems, or necessary to use in emergencies or epidemics, or to save lives.

2. There are problems in access to those drugs and medical supplies, as well as creating a high financial burden that the National Health Insurance Systems cannot afford.

**Question 6: How does Thailand intend to improve the decision-making processes to implement the Government Use of Patents in order to make it more transparent?**

We have formally and informally requested advice from our trade partners who had concerns on the transparency of implementation. We would like to learn which steps are not transparent, and are ready to improve. However, so far we have not received any advice, verbally or officially. The only critique that we have heard is that we enter into discussion with the patent-holders, which we have already done, since before the first batch of the Government Use of Patents between 2004 and 2006. The result in the case of Imatinib is a good example of our attempts in this area.

We have also requested that the Director General of WHO, based on the World Health Assembly resolution WHA 60.30, send a team of technical experts from WHO, together with relevant organizations like WTO, UNCTAD, and UNDP, to analyze our implementation processes and provide technical guidance for better and more transparent processes. This group of experts worked in Thailand from February 4 to 6, 2008 and met with all relevant stakeholders. The expert group has presented a very good report, which provides systematic approaches toward implementing TRIPS flexibilities for increased access to essential medicines, as well as other possible non-TRIPS-related strategies. *The group has not described any non-transparency of the processes that Thailand has implemented with the Government Use of Patents. Thailand has actually implemented all the necessary steps suggested in the report. Some actions, like the prior negotiation, were more than what suggested in the report.* The report also advises Thailand to apply TRIPS flexibilities both before and after granting the patent.

The implementation of the TRIPS flexibilities may be a normal practice in developed countries, but they are quite new for developing countries like Thailand. So we should regard this movement as a social innovation to achieve better access to essential medicines, and as a learning experience to strengthen social understanding of the issue. It should be used as a mechanism to engage constructively all stakeholders, including the patient groups, the drug industry, the other public sectors, and relevant IGOs, to solve the problem of inadequate access to essential medicines under the universal health care policy.

**Question 7: Will this decision be a reason for the USTR to consider moving Thailand from the Priority Watch List to the Priority Foreign Country list, and if so, how is this going to affect Thai exports to the US?**

The rationale behind moving Thailand from the status of Watch List (WL) to Priority Watch List (PWL) last July was mainly due not to the implementation of the Government Use of Patents, but was based more on inadequate enforcement for the protection of other forms of intellectual property, such as the illegal production and distribution of optical disc media, books, and entertainment and business software. For the implementation of the Government Use of Patents on drugs, the concern was on transparency and due process, which had never been clarified on any specific point, so far, except to request that Thailand negotiate with the patent-holders. The discussions with the patent-holders have been carried out intensively, as described in questions 1 and 2. The success in the case of Imatinib shows that it is possible to achieve a good and constructive solution, if the patent holder has a real commitment to support the Thai people's right to universal access to essential drugs under the universal health care scheme.

The U.S. Trade Act, Article 301, provides conditions for listing trade partners as Priority Foreign Countries when it shows *the most onerous and egregious acts, policies, and practices which have the greatest adverse impact (actual or potential) on the relevant U.S. products.*

The implementation of the Government Use of Patents on seven essential drugs complied completely with the international and national legal framework. Furthermore, the four anti-cancer drugs for which Thailand decided to implement the Government Use of Patent are all non-U.S. products. Thus, the USTR does not have any basis for putting Thailand on the Priority Watch List as regards the issue of Thailand's decision to implement the Government Use of Patents.

If there is still concern over the lack of transparency and due processes, then Thailand will need to be advised clearly and specifically on how to improve in these areas.

The data from the Ministry of Commerce shows that the value of export of those goods whose GSP were abolished in last July continue to increase, not decrease. All evidence indicates that the significance of the GSP in supporting Thai exports to the U.S. is constantly declining, and will gradually be totally abolished or minimized in the near future. On the contrary, the negative implications on the access to essential medicines from the market exclusivity of the patented products are increasing, and will generate more and more obstacles to the access of essential medicines in the near future.

**Question 8: The Prime Minister instructed the Ministry of Public Health to hold further discussion with the Ministry of Commerce and the Ministry of Foreign Affairs regarding Thailand's position on the implementation of compulsory licensing for government use. Has this happened, and what was the outcome?**

The Ministry of Public Health (MoPH) on August 24, 2007, held a discussion with the Ministry of Commerce and the Ministry of Foreign Affairs regarding Thailand's position on this issue. Participants were from the Ministry of Commerce, the Ministry of Foreign Affairs, the National Health Security Office, the Ministry of Labour, the Ministry of Science and Technology, the AIDS Access Foundation, the Thai Network of People Living with HIV/AIDS, the Cancer Care Network and Oxfam, Great Britain. The meeting reached a consensus as follows (annex 14):

1) Thailand honors its obligation under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Doha Declaration on the TRIPS Agreement and Public Health. *However, it is stated in the Agreement and the Declaration that in the circumstances of public health crises, or where the public interest arises, public health interest shall be given priority and put before trade interest, and that the WTO members have the right to use TRIPS flexibilities and the freedom to determine the grounds upon which such flexibilities are used;*

2) The Thai government has an obligation under the Constitution of Thailand B.E. 2550 and the National Health Security Act B.E. 2545 to ensure that all Thais have access to medicines listed on the National List of Essential Medicines. This is achievable through various measures such as budget raises and the promotion of the rational use of drugs, including the use of flexibilities granted under the TRIPS Agreement, the Doha Declaration and the Thai Patent Act B.E. 2522 as amended by the Patent Act (No.2) B.E. 2535 and the Patent Act (No.3) B.E. 2542;

3) Thailand has a policy of using TRIPS flexibilities embodied in the TRIPS Agreement, the Doha Declaration and the Thai Patent Act *only when necessary*. This is to achieve our ultimate goal of availability of essential medicines for our people, according to the right conferred under the National Health Security Act. However, the measures will be *implemented with due consideration and not in an indiscriminate manner or for frivolous reasons*. Furthermore, negotiations with pharmaceutical companies will be built on respect for our mutual interest in bringing improvements to Thailand's public health services.

4) Section 51 of the Thai Patent Act defines the right of the Minister, Permanent Secretary and Director-General of any ministry, bureau or department of the Government to issue a compulsory license in order to carry

out services for public consumption, and in case of urgency, e.g., to increase access to essential medicines for the Thai people. Therefore, *it is not possible for anyone to announce or commit to any person or country that Thailand will not implement the Government Use of Patents on pharmaceutical patents in any circumstances.* Doing so is deemed to be a neglect of duty or failure to exercise the rights established by the law to safeguard public interest and public health, and can incur a criminal charge.

5) There is no country or government in the world that would renounce its rights to implement a Government Use of Patents on any drug patent. On the contrary, developed countries grant more compulsory licenses than developing countries.

In addition, in late December 2007, the Ministry of Commerce advised the Deputy Prime Minister and Industry Minister, H.E. Kosit Panpiemras, to hold discussion between three ministries—the Ministry of Public Health, the Ministry of Commerce and the Ministry of Foreign Affairs—about the implementation of the Government Use of Patents by the Thai government. The meeting was scheduled on January 3, 2008. The Ministry of Public Health’s officials, led by Dr. Vichai Chokewiwat, Advisor to the Public Health Minister, Chair of the Government Pharmaceutical Organization (GPO) Board and Chair of the Committee to Support the Implementation of the Government Use of Patents, and Dr. Siriwat Tiptaradol, Secretary General of the Thai Food and Drug Administration (FDA), and their team, who were vested **with full powers and duties**, had planned and held several meetings in preparation for the discussion. Unfortunately, however, the discussion was postponed without a new date set.

**Question 9: How can we be sure that the drugs obtained under the Government Use provision will not slip through the system into the market, or how will we prevent the practice of diversion, i.e. patients selling the drugs to pharmacies or private hospitals?**

The four compulsory licensed drugs are anti-cancer drugs, of which over-the-counter sale is strictly prohibited. They are available by medical prescription only and must be prescribed by specialist doctors. Moreover, they are live-saving drugs for cancer patients. Some of them are intravenous medications which must be administered by doctors or specialist nurses. So, there should be no worry that patients who will receive these licensed drugs under the national health security system will sell the drugs to pharmacies. Doing so will only do harm to their lives, for they will have traded their live-saving medications. Furthermore, no pharmacy will buy them because it is illegal; they are prescription-only medicines, and hence are not available for sale or distribution as mentioned above.

For hospitals, these drugs will be supplied to contracted hospitals under the national health security system only. Non-contracted private hospitals will not be able to buy these licensed drugs from the Government Pharmaceutical Organization (GPO). In addition, these drugs are dispensed under strict control, and every prescription is recorded to ensure transparency and accountability. This is to prevent the drugs from slipping through the system. It is quite certain that the drugs obtained under the Government Use provision for public consumption under the national health security scheme will not be used for commercial purposes, which is inconsistent with the Thai patent law and international agreement on intellectual property rights.

All the drugs licensed under the Government Use provision for use in the National Health Security Office's universal health scheme are procured by the Government Pharmaceutical Organization (GPO) under its aggregate drug procurement plan (bulk purchasing) and dispensed under the **Vendor Managed Inventory (VMI)** system. GPO will procure the drugs and supply them according to the demand of each hospital, to make sure that all the licensed drugs will not slip through the system.

**Question 10: As anti-cancer drugs are live-saving drugs, how can we be certain that the generic copies of these drugs will be equivalent in quality to the patented products?**

The World Health Organization (WHO) has a system of prequalification only for anti-retrovirals, anti-TB and anti-Malaria drugs. The system does not cover other drugs, including anti-cancer drugs. As a result, the drug quality assurance of these generic copies, whether derived from the Government Use provision or not, is subject to Thailand's drug qualification standards as well as the quality control of the companies and the competent officials of the exporting countries. The Thai drug qualification standards are follows:

1) *Drug registration system*: the Department of Medical Science and the Food and Drug Administration (FDA) are responsible for drug registration. They also have established a specific drug approval process for generic copies derived from the Government Use provision to ensure fast and rigorous implementation. They expedite the approval process and carry out rigorous examination of applications and drug samples, even by visiting generic drug manufacturing facilities in India to evaluate their manufacturing standards and quality;

2) *Post-import surveillance system*: the Government Pharmaceutical Organization (GPO) conducts quality surveillance of randomized samples of imported drugs to ensure drug quality before distributing them to hospitals. It also regularly performs quality surveillance of randomized samples of drug products stored in hospitals' warehouses;

3) *Drug quality reporting system*: medical professionals who prescribe these drugs can report any quality problems with the imported drugs to the Food and Drug Administration (FDA) immediately, and the FDA will take immediate action to investigate the problems and collect the drug samples for further analysis.

Through these rigorous and ongoing quality control systems, we are confident that the drugs imported under the Government Use provision are equivalent in quality to the patented products.