

# When patent rights may not be enforceable:

## The case of Kwao Krua patent

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### Abstract

In May, 1999, a Thai patent was granted on a composition containing Kwao Krua and several other ingredients. Due to the way the claims were written, many people were confused and were led to believe that the patent granted an exclusive right for all products containing over 10 per cent of Kwao Krua. It turns out that the patent examiners did not have access to the traditional medical non-patent literature. After the prior arts were revealed to DIP, what could be done with the Kwao Krua patent. In the long run, what could be done to prevent such confusion and problem from happening again. In conclusion, even when one is a patent holder, if the invention cannot satisfy the requirements for patentability in the first place, it will not hold up and the patent rights may not be enforceable. Only new, useful, and non-obvious inventions not on the exclusion list deserve patent protection, which will stimulate more technological invention and benefits the society.

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<sup>1</sup> This paper is the original edition (V1.00) that appeared in the Intellectual Property and International Trade Law Forum (Special Issue: Second Year Anniversary of the Central IP&IT Court - 1999) The author, who is also the copyright owner, wrote this paper in his spare time. Any opinion expressed here is the author's own opinion and may not necessarily be shared by the Central IP&IT Court or Chulalongkorn University Intellectual Property Institute. The author has attempted to the best of his ability to write and proofread this article but cannot offer any warranty as to the accuracy, completeness, or timeliness of the information provided, or as to the suitability of application to the reader's need. Furthermore, this article only deals with the intellectual property issues and not to the safety issues of the matter. Medicinal plants may have devastatingly undesirable side effects so readers are encouraged to take warning labels and governmental regulations seriously. The author will be indebted to any reader who reports any errors, omissions, or otherwise any possible improvements to this article. Abbreviations: DIP = Department of Intellectual Property, IPITC = IP&IT Court = Intellectual Property and International Trade Court, KK = Kwao Krua, WKK = white Kwao Krua, RKK = red Kwao Krua.

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# 1. Introduction

In mid 1999, Thai patent No. 8912 was granted on a composition of Kwao Krua, an indigenous medical herb with many potentials on human sexuality. Due to some peculiarities in the way the claims were written, several people believed or were led to believe that one of the claims gave complete monopoly on all products containing from 10 to 100 per cent Kwao Krua. The patent owner, through the help of a prominent law firm, actually issued public warnings that they would enforce their rights. Several people were concerned how such a sweeping right could be granted to a private company.<sup>3</sup> Others were concerned whether such an incident will ever happen again to other medicinal herbs of Thailand. This article attempts to understand how such patent rights were granted, what rights were actually granted, and what could be done in light of prior arts that were not accessed by patent examiners. Further preventive measures will be suggested to reduce the possibility of such confusion happening again.

## 2. The Potency of Kwao Krua

Several types of Kwao Krua, e.g. white, red, black, and gray, are known medicinal herbs of Thailand. They are flowering plants in the family *leguminosae*. In Thailand, family *leguminosae* consists of 102 genera and 614 species that can be grouped into 3 subfamilies: *Mimosoideae*, *Caesalpinioideae*, and *Papilionoideae*. Kwao Krua belongs to the latter subfamily.<sup>4</sup> Owing to their effects related to breast enlargement in females and to penis erection in males, the financial gains to anyone who can attain monopoly, even limited monopoly, in this business is enormous.

### 2.1 The White Kwao Krua

White Kwao Krua (*Pueraria mirifica*) is a twining, long-life herbal plant that exists in Thailand in the northern and western part of the country. Kwao Krua may be found in association with moderate-size trees ranging from timber wood to bamboo in the deciduous rain forests. Each plant has only three leaves. The root is between 0.5 and 2 meters long before it becomes a tuber, which can attain the size of a coconut or a water melon. On maturity, the tubers of Kwao Krua enlarge and accumulate several chemicals known as “phytoestrogens,” i.e. female hormone analogs produced by plants.<sup>5</sup>

While several other edible plants, including Soya (*Glycine max*) and alfalfa (*Medicago sativa*), contains traces amounts of phytoestrogens, White Kwao Krua contains phytoestrogens in a more concentrated form.<sup>6</sup>

In the early 1960s, British researchers reported potent estrogenic effects of miroestrol, the key phytoestrogen of White Kwao Krua, on ovariectomized rats, immature female rats, and female human volunteers.

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<sup>3</sup> For example, the Association of Traditional Pharmaceutical Manufacturers and Sellers wrote a letter on September 9, 1999, asking the Ministry of Commerce to revoke the Kwao Krua patent. DIP (1999c)

<sup>4</sup> Subcharoen (1999) p. 3.

<sup>5</sup> Luong-Anusarnsoontorn (1931).

<sup>6</sup> Further information in this section was adapted from Cherdshewasart (1999).

Recently, Cherdshewasart (1999) conducted food supplement trials on human volunteers, where up to 800 mg of White Kwao Krua was given daily for two months. It was reported that White Kwao Krua promoted firmness of the breast in case of “fallen bust” and enlargement of the breast in case of small or deformed breast. The enlargement varied from 1 to 3 inches among 90 per cent of the subjects in the experimental group. Side effects included a brief period of drowsiness and prolonged menstruation period in subjects consuming too much White Kwao Krua for too long. Further tests for short, medium, and long-term side-effects are still pending.<sup>7</sup>

Furthermore, the same author also reported positive results on topical application of a White Kwao Krua extract cream for two months. Comparable firmness and/or enlargement was felt by 27 out of 30 volunteers in a shorter time required by oral administration. The side effects are not mentioned in the paper.

## 2.2 The Red Kwao Krua

While White Kwao Krua has business potentials for females, Red Kwao Krua seems to have such commercial promises for males that it has been called the “Herbal Viagra.”<sup>8</sup>

Red Kwao Krua (*Butea superba*) can grow as an independent plant in the shape of a small bush. It is often found in the mountains in the northern part of Thailand. Each stem has three leaves. The roots of the mature plant are 8 to 9 inches long before they turn into tubers in the shape of elephant tusks. On cutting, the tubers reveals many red fibers and leaks red sap.<sup>9</sup>

Animal studies in 10 adult male mice force-fed for 10 days with 4 mg/kg of Red Kwao Krua showed no short-term abnormality. Human studies on 3 male volunteers (age 20 to 55) receiving up to 1.6 g/day of Red Kwao Krua for 2 months showed dramatic penile responses such as induction and elevation of early morning erection, erection frequency, penis strength, prolongation of erection, post-ejaculation erection, and intercourse frequency. The response was found to be dose-dependent, while a few volunteers felt neckache and backache.<sup>10</sup> Further tests for short, medium, and long-term side-effects are still pending.

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<sup>7</sup> In early in 1999, a research team at Ramathibodi Hospital got together with the team from the Institute of Thai Traditional Medicine, with financial support from the Thai Traditional Medicine Foundation and technical support from Department of Medical Sciences at the Ministry of Public Health, started animal testing trials for acute and semi-chronic toxicology of Kwao Krua produced by Dr. Cherdshewasart. The data obtained will be used in the future in designing the clinical testing on humans. See TTM (1999).

<sup>8</sup> Cherdshewasart (1999). Viagra (sildenafil citrate) is a registered trademark of Pfizer, Inc.

<sup>9</sup> Luong-Anusarnsoontorn (1931)

<sup>10</sup> Cherdshewasart (1999). Note that the research mentioned in this reference was not conducted at Chulalongkorn University and therefore was not reviewed by any bio-ethics committee. Chulalongkorn University has taken an official position that in this Kwao Krua case, the University would not seek to share any ownership or benefits from intellectual property with the inventor.

## 2.3 The Black Kwao Krua

The Black Kwao Krua plant looks similar to the Red Kwao Krua but with smaller leaves. The sap is black. It is said to be more potent than the white or the red Kwao.<sup>11</sup>

## 2.4 The Gray Kwao Krua

This Kwao Krua looks almost identical to the Black Kwao Krua except the flesh and the sap looks gray instead of black. The plant is rare and the tuber is only as large as a potato.<sup>12</sup>

## 3. The first Thai patent granted on Kwao Krua

In 1998, a couple of patents application were filed with the DIP on inventions related to Kwao Krua. The first application was the only one that has been granted so far and is the subject of this article.

On July 31, 1998, a Thai patent application was filed by Matana Panich Chiang Mai Co., Ltd. on “Medicinal herbal Composition from Kwao Krua.” The inventor was listed as Mrs. Mantana Uawitaya. After less than 6 months of preliminary examination, the patent application was published in the Patent Publication Gazette on January 25, 1999. (See Display 1.) Then substantive examination began.<sup>13</sup> Amazingly, less than three weeks from the dead line of the contest period, Thai patent No. 8912 was granted in respect of this invention on May 10, 1999. The claims of this patent are listed in Display 2.

After this patent was granted, Matana Panich Chiang Mai Co., Ltd. put up advertisement in popular local newspapers in the form of notices from a prominent law firm, informing the public and other producers of Kwao Krua products that the company now has the exclusive rights and are determined to enforce them.

Once the public has learned of the Kwao Krua patent, there were outcries from other competing pharmaceutical and cosmetic companies that believed the Government had granted away patent rights on all products containing over 10 per cent Kwao Krua, which practically covered all Kwao Krua products on the market. A trade association of traditional pharmaceutical practitioners even complained to the Deputy Minister of Commerce that the Ministry should take steps to revoke the Kwao Krua patent<sup>14</sup> based on the prior art published in 1931.

The intellectual community also voiced concerns in the form of academic seminars.<sup>15</sup> Background information on Kwao Krua was publicized and research data were exchanged at these meetings. The emphasis was put on the biosafety regulation issues of Kwao Krua.

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<sup>11</sup> Luong-Anusarnsoontorn (1931)

<sup>12</sup> Ibid.

<sup>13</sup> Thai Patent Act 1979 (last amended in 1999) Article 29 and Article 31.

<sup>14</sup> DIP (1999c).

<sup>15</sup> such as the one reported in TTM (1999).



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(54) Name of Invention Herbal Composition from Kwao Krua

#### (57) Summary of Invention

Disclosed are medicinal herbal compositions from White, Red, and Black Kwao Krua consisting of ingredients from milk and animal milk products and/or ingredients from sweet food substance and/or ingredients from herbal medicinal plants and/or other ingredients, singly or in combination for treatment of some diseases and health promotion.

#### Claims:

1. Medicinal herbal compositions comprising of the following ingredients:

1.1 White Kwao Krua and/or Red Kwao Krua and/or Black Kwao Krua

1.2 Milk and products from milk of animals in the category of cow, water buffalo, and sheep

1.3 Food sweetener consisting of white cane sugar, red cane sugar, and solid palm sugar

1.4 Plants of medicinal herbal type Makampom [*Phyllanthus emblica*], Samor Thai, Samor Pipek [*Terminalia bellirica*]

1.5 Colorant, fragrant, flavoring, characteristics modification agent, excipient

2. Medicinal herbal compositions according to claim 1, where the ingredients are in the following amounts:

### Display 1: Publication of the Kwao Krua Patent Application

Note that only claim 1 and the first two lines of claim 2 are visible in the publication document. Translated from an official document in the Thai language.

No.	Claims of the Kwao Krua Patent (Thai Patent No. 8912)
1	<p>Medicinal herbal compositions consisting of the following ingredients:</p> <p>1.1 white Kwao Krua and/or red Kwao Krua and/or black Kwao Krua</p> <p>1.2 milk and/or product from milk of animals that belong to the group of buffalo, water buffalo, goat</p> <p>1.3 food substance with sweet taste</p> <p>1.4 ingredients from herbs</p> <p>1.5 ingredients for modifying the color, odor, taste, or characteristics of the composition; excipient</p>
2	<p>Medicinal herbal compositions according to claim 1 consisting of the said ingredients in the following quantities:</p> <p>2.1 white Kwao Krua and/or red Kwao Krua and/or black Kwao Krua: 10 to 100 per cent of the weight of the Kwao Krua medicinal herbal composition product</p> <p>2.2 milk and/or product from milk of animals that belong to the group of buffalo, water buffalo, goat: 0 to 50 per cent of the weight of the Kwao Krua medicinal herbal composition product</p> <p>2.3 food substance with sweet taste from the following list: honey, sugar cane juice, sugar, white granulated cane sugar, brown granulated cane sugar, palm sugar: 0 to 50 per cent of the weight of the Kwao Krua medicinal herbal composition product</p> <p>2.4 ingredients from medicinal herbs Makampom [<i>Phyllanthus emblica</i>] and/or Samor Thai and/or Samor Pipek [<i>Terminalia bellirica</i>]: 0 to 50 per cent of the weight of the Kwao Krua medicinal herbal composition product</p> <p>2.5 ingredients for modifying the color, odor, taste, characteristics, or the bolus (excipient) of the composition; ingredients acting as base, filler, or carrier. 0 to 25 per cent of the Kwao Krua medicinal herbal composition product</p>
3	<p>Medicinal herbal compositions from Kwao Krua according to either claim 1 or 2 that are added with pharmaceutically accepted potentiating substances that do not harm the Kwao Krua composition produced according to either claim 1 or 2.</p>
4	<p>Medicinal herbal compositions from Kwao Krua according to either one of the claims 1 to 3, where the potentiating substance is alcohol.</p>
5	<p>Medicinal herbal compositions from Kwao Krua according to either one of the claims 1 to 4 that are further added with carriers, coloring agents, odor modifying agents, taste modifying agents, filler, or binders that are pharmaceutically accepted and do not harm the quality or the potency of the Kwao Krua medicinal herbal composition produced according to either one of the claims 1 to 4.</p>
6	<p>Medicinal herbal compositions from Kwao Krua according to either one of the claims 1 to 5 where the coloring agents are cosmetically accepted substances.</p>

No.	Claims of the Kwao Krua Patent (Thai Patent No. 8912)
7	Medicinal herbal compositions from Kwao Krua according to either one of the claims 1 to 6 that are further added with pharmacologically accepted substances that can neutralize the natural toxicity of white, red, or black Kwao Krua and do not harm the quality or potency of the Kwao Krua herbal composition produced.
8	<p>Process for producing the Kwao Krua medicinal herbal composition according to either one of the claims 1 to 7 consisting of the following steps:</p> <p>8.1 wash, skin, cut, leave in the open until dry, grind into powder the ingredients according to claim 1.1.</p> <p>8.2 wash, clean, leave in the open until dry, and grind into powder the ingredients according to claim 1.4.</p> <p>8.3 add one or more of the ingredients according to claim 1.2 and/or 1.3 and/or 1.5.</p> <p>8.4 yielding Kwao Krua medicinal herbal compositions with characteristic consistency according to the ingredients used, which may be powder, liquid, scoopable syrup, or kneadable paste.</p> <p>8.5 form into final product according to the ingredients and suitability for use, which may be in the forms of pill, bolus, capsule, liquid, or syrup.</p>
9	Use of Kwao Krua medicinal herbal composition according to either one of the claims 1 to 7 in the production of pharmaceutical substances that are effective in the treatment of certain diseases consisting of sinusitis, gas in the stomach and gastrointestinal tract, hair loss, and insomnia; and are effective, similar to female or male sex hormone, in health-promotion of skin and sickness at menopause in that they tighten the skin, eliminate mylasma or freckles on the skin, enlarge and tighten the breasts, relieve muscle ache and age-related optical and auditory nervous degenerations, and enhance sexual potency in males and females.

## **Display 2: Claims of the Kwao Krua patent.**

The claims of Thai patent number 8912 are translated and shown here in its entirety.

## **4. Difficulties with the Kwao Krua patent**

Aside from the fact that there may be significant health risks involved in using the products, the Kwao Krua patent posed a few intellectual property problems that made many Thai people upset at DIP, at the assignee, and at the patent system as a whole. Here we will divide the problems into 5 groups as follow:

### **4.1 Urgency of the Substantive Examination and Patent Grant Process**

Normally, a Thai patent application takes about 1 to 2 years of preliminary examination plus at least 90 days of publication period plus about 3 years of substantive examination, making the total patent prosecution wait to be about 5 years. The DIP has been trying to shorten this wait but for quite a few patent applications, by the time the



patent is granted, the patent owner has to pay the maintenance fees for the 5-year milestone.

In the case of Kwao Krua, the procedures seemed to be executed at a lightning speed, i.e. the total time from filing to granting of patent was less than 10 months. With a couple of weeks allowed for substantive examination, one cannot help wonder why the examination went on so urgently.

## **4.2 Inconsistent and Problematic Way of Writing the Dependent Claim (Claim 2)**

This problem has to do with the way that Claim 2 (the dependent claim) is written in comparison to Claim 1 (the independent claim). (Compare Display 1 and Display 2.) Since Claim 2 makes claim 1 more specific by giving ranges of concentrations of ingredients, the percentage numbers given for the concentrations must never become zeroes. Otherwise, Claim 2 would be in conflict with Claim 1. As it is written, Claim 2 gives four ranges of other ingredients besides Kwao Krua that include zero percentages. If one reads only Claim 2 (which most lay people would), he may be misled to believe that there is a possibility that all other percentages in Claim 2 besides Kwao Krua could become zeroes. Therefore, Claim 2 seems to give monopoly to the patent owner for any product that contains over 10 per cent Kwao Krua. This misconception is in the commercial interest of the patent holder.

Even more interesting is the normal practice that patent publications includes only the first claim. If one sees only the publication and not the complete claims, he would not be able to detect any irregularities mentioned above. Therefore, the inconsistency had been “hiding” all along, undetectable to the public until after the patent was granted.

## **4.3 Lack of novelty of Kwao Krua<sup>16</sup>**

Since it is a general knowledge in Thailand, especially for those interested in medicinal herbal plants, that Kwao Krua is quite a potent substance with regard to human sexuality, many people, especially lay people, naturally wondered how a private company could obtain a patent on such a medicinal plant. This circumstance could create bad publicity for DIP and mistrust of the patent system in general.

## **4.4 Obviousness of the Invention<sup>17</sup>**

Again, many people in the circle of traditional medicine objected the grant of this patent on the ground that the invention involves all known ingredients, without any unexpected or synergistic merit of the composition. Superficially, it looks like someone would only need to open the textbook of Luong-Anusarnsoontorn (1931), copy a section, and modify a few words to form the first claim of this patent.

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<sup>16</sup> According to Article 5 of the Thai Patent Act of 1979 (last amended 1999), patentable inventions must be new, possessing inventive step, and capable of industrial applicability. Criteria for novelty is covered in Article 6 of the Patent Act and in DIP (1999b) Section 1.4, pp. 4-12.

<sup>17</sup> Inventive step is covered in the Article 7 of the Thai Patent Act of 1979 (last amended 1999) and DIP (1999b) Section 1.4, pp. 13-17.

Formulation and Condition of Use	Claimed Benefit
<b>Kwao Krua by itself</b> (incompatible with pickled food)	
One 2 mm diameter of White Kwao Krua at bedtime (or) One third 2 mm diameter of Red Kwao Krua for 20-30 days Take 3 showers a day Follow 5 commandments (no alcoholic drink) Not for young people.	treatment of fatigue, skinniness, lack of sleep, loss of appetite 70-80 years old women gaining weight, menstruate, and have stiff nipples men having stiff nipples and muscles body
<b>Kwao Krua taken orally with milk or milk products.</b>	
Red Kwao Krua beaten into powder taken orally with cow milk.	clear mind, good memory, tender skin, longevity, healthy
Water buffalo milk soaking with Kwao Krua used as hair lotion Apply sesame oil	white hair turning black no more white hair no more skin wrinkles thin hair becoming thick
Milk soaking with Kwao Krua, applied on an eye that has been blind and patched for 6 months Taken orally twice daily Take showers 3 times a day	blind or cloudy eye will become clear
Kwao Krua taken orally with cow milk or goat milk One bottle of milk mixed with powder Kwao Krua to form round balls of about 1 cm in diameter. Air dry. Taken 1 ball before bedtime.	
Boil water buffalo milk and mix with Kwao Krua. Take a ball of about 2 mm in diameter	
Kwao Krua taken with the milk of cow or water buffalo Form balls of about 1 cm in diameter	youth
Kwao Krua taken orally with yogurt	longevity, no gray hair, no falling teeth, no wrinkled skin
<b>Kwao Krua taken with sweet substances</b>	
Kwao Krua taken orally with butter or honey	longevity, excellent memory, ability to satisfy 1,000 women
<b>Kwao Krua taken orally with medicinal herbs</b>	
Kwao Krua taken orally with Makampom, Samor Thai, Samor Pipek One part by weight of the three herbs are beaten to powder.	bad eyesight will improve

Formulation and Condition of Use	Claimed Benefit
One part by weight of Kwao Krua. Add honey to form balls about 0.5 mm in diameter. Take twice a day before meals. Take showers 3 times a day.	
<b>Kwao Krua taken with other ingredients</b>	
Kwao Krua taken orally with partially fermented rice water	tender skin like angels
<b>Kwao Krua taken with any ONE of these ingredients</b>	
<ul style="list-style-type: none"> <li>- [Milk] water buffalo milk, cow milk, goat milk, yogurt milk</li> <li>- [Sweetener] honey, brown sugar, cane sugar sap;</li> <li>- [Medicinal herb] dried Makampom, Dried Samor Thai, Dried Samor Pipek;</li> <li>- [Coloring, Flavoring, Binder, Base] butter, [honey], water flowing out of a rice cooking process</li> </ul>	
<b>Kwao Krua taken in combination with several other ingredients</b>	
Kwao Krua mixed with all of the following ingredients and formed into small balls: <ul style="list-style-type: none"> <li>- [Milk] goat milk, water buffalo milk, cow milk</li> <li>- [Sweetener] honey, brown sugar, cane sugar sap, granulated cane sugar,</li> <li>- [Medicinal herb is not mentioned in this formulation.]</li> <li>- [Coloring, Flavoring, Binder, Base] butter, [honey]</li> </ul>	strength, no gastrointestinal disturbance, longevity

### Display 3: Prior arts of Kwao Krua formulations

Translation from excerpted Thai text (Luong-Anusarnsoontorn, 1931). Several formulations have been grouped and arranged according to the ingredients to be taken orally with Kwao Krua. Note that DIP stated that this prior art was available to the examiner after the patent was already granted.

## 5. Analysis of the Problems

### 5.1 Urgency of the Substantive Examination and Patent Grant Process

From the viewpoints of DIP officials, faster service should be an asset instead of a liability. As for the source of this rapidity, they offer two explanations:

- The policy was changed from requiring prior art search conducted at a foreign patent office, e.g. Australian Patent Office, to search performed by DIP's own examiners. This new policy saves time and money (almost about US\$1,000).
- In the case of medicinal herbal plants and products thereof, there is little, if anything, to search. Unpatented formulations in Thai traditional medicine is outside the reach of patent examiners. Therefore the search could be performed very rapidly.

## **5.2 Inconsistent and Problematic Way of Writing the Dependent Claim (Claim 2)**

Perhaps due to the rapidity of the examination process, an error was either made or overlooked. The concentration range in the dependent claim should not be allowed to reach exactly zero per cent. To rectify this error, DIP took the opportunity to educate inventors and entrepreneurs that a dependent claim must be read in light of the independent claim to which it is attached. Therefore, the zero per cent concentrations in the dependent claims cannot be read literally but have to be read "approaching zeroes" to be consistent with the independent claim.

Despite the rectification from DIP, considerable confusion has been created in a wide circle owing to the public notification from the patent owner's law firm. During that time, several people actually believed that the patent owner had an exclusive right to make, use, and sell all products that contained over 10 per cent by weight of the White and/or Red and/or Black Kwao Krua.

## **5.3 Lack of novelty of Kwao Krua<sup>18</sup>**

As mentioned earlier, the DIP maintained that at the time of substantive examination, no Thai traditional medical textbook or formulations compendium or pharmacopoeia like Luong-Anusarnsoontorn (1931) was available to the examiner. No novelty question had never arisen.

Now, with information from Luong-Anusarnsoontorn (1931), the DIP maintains that the novelty of the Kwao Krua patent still has not been destroyed.

In order for the invention to lack novelty, the prior art has to be either exactly or narrower in scope than the invention.<sup>19</sup> Two prior arts closest to the invention are the last two rows of Display 3. In the row before last (Kwao Krua taken with any ONE of these ingredients), all ingredients are mentioned but not mixed. In the last row (Kwao Krua taken in combination with several other ingredients), all ingredients are mixed but the additional medicinal herbs are missing. Since the scope of the closest prior art is still broader than the invention, novelty is not destroyed.

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<sup>18</sup> At the start of an examination, searches have to be performed on (1) Prior domestic patent applications to implement the "first to file" principle, (2) State of the art search on granted patents worldwide, (3) General technical background search on non-patent literature.

<sup>19</sup> DIP (1999b) Section 1.4, pp. 10-12. This Manual is patterned after that of the European Patent Office.

## 5.4 Obviousness of the Invention

In order for an invention to possess a significant “inventive step” over the prior art, DIP has set up about 15 criteria for non-obviousness test.<sup>20</sup> Nevertheless, without any prior arts to compare to, the invention was pronounced non-obvious.

If the information from Luong-Anusarnsoontorn (1931) had been available to the patent examiner during substantive examination, it would have been interesting to see whether the patent examiner would reject the patent application based on the prior art on the last row of Display 3 and the fact that the inclusion of three medicinal herbs did not satisfy any one of the non-obviousness criteria.

Now, armed with the information from Luong-Anusarnsoontorn (1931), DIP has internally determined that the Kwao Krua patent lacks an inventive step. The addition of the three medicinal herbs to the prior arts shown in the last row of Display 3 is viewed as a trivial combination of known prior arts without any unexpected results. The broadening of concentration range of ingredients compared to the prior arts does not make this invention non-obvious. So far, the Department seems to be waiting for somebody to bring the case to the Intellectual Property and International Trade Court.<sup>21</sup>

## 5.5 Summary of the Long-term Problems

Although Kwao Krua still has a long way to go with respect to biosafety testing, here we will summarize only the problems related to the prosecution of patent examination and enforcement of patent rights.

- DIP lacks search capability on non-patent literature, including medicinal herbal plants.
- DIP needs to upgrade the judgment of its patent examiners, even with the existence of an office Manual. The upgrade may be in the following areas:
  - Technical background and expertise of patent examiners
  - Skill and vision of patent examiners, which are the results of extensive experience in making sure the system functions according to the ultimate principle of stimulating inventive activities, technology transfer, and technological progress for the benefit of society.

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<sup>20</sup> An invention needs to satisfy at least ONE criterion to qualify as being non-obvious. The criteria headings include: effect of design/form, task, selection, requirement, simplification, concentration of development steps, success, scientific & technical research, progress, obvious results, achievements, cost reduction, surprising results (better yields, better quality product, less toxic intermediates, possible reuse, new pharmacological use, unexpected combination, unexpected technical characteristics, etc.) , etc. DIP (1999b) Section 1.4, pp. 13-17. The difference between the invention and the prior art must not be obvious to those with ordinary skill in the art. Patent Act, Article 7.

<sup>21</sup> According to the Thai Patent Act of 1979 (last revised 1999) there are two standard ways of post-grant narrowing of patent claims. The patent owner may initiate the process for revoking some or all of the claims according to Article 53. Alternatively, if the patent is not actually complete, an affected individual or a State Attorney may petition the IP&IT Court to revoke the patent according to Article 54.

- DIP needs a more transparent examination process of patent applications in order to restore trust in the system. All patent applicants should feel that they are treated equally with respect to the rapidity and quality of the examination.

## 6. Preventive Measures

We may be able to prevent the long-term problems summarized in the last section by taking the following actions:

- DIP personnel must be on top of the designated technical field. Existing examiners should receive periodic technical training. New examiners should be recruited from applicants with Master and Doctoral degrees. In order to increase the quality and number of examiners, more budgets will be needed. This will involve reorganization in the structure and administration of DIP itself. The Department must formulate decent career paths for patent examiners in order to boost the prestigious image of these examiners in the eyes of youngsters and college graduates. Furthermore, patent examiners must undergo periodic training by qualified trainers on new techniques, situations, and issues.
- Patent examiners must have access to traditional medical formulations and textbooks. There should be cooperation between DIP and the Institute of Thai Traditional Medicine in this regard. DIP should also determine which other technical field(s) will need such cooperation with external agencies.
- DIP should make its procedures more transparent in order to secure more trust in the system. A quality control system should be established. If there exists any Patent Office Accreditation Program, DIP should consider joining such a program.
- DIP should take advantage of this Kwao Krua patent case to educate the public of the patent system and how it can be used correctly to benefit the society.
- Private lawyers and intellectual property counselors should be aware of their social responsibilities. They should advise their clients about the proper way to handle the exclusive rights granted by a patent and should not communicate to the public in such a way to broaden the scope of the patent rights to cover something that has not actually been granted. This is also in the interests of the clients and their existing and potential competitors or licensees.

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