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Contents

Five years after its launch in 2001, the 30-Baht Health-Care Scheme–widely perceived as a pro-poor program—is questioned whether it has fulfilled the needs of the poor as promised. See related article on page 3.

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Universal Health Care Coverage: Impacts of the 30-Baht Health-Care Scheme on the Poor in Thailand

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I. BACKGROUND

In late 2000, the "Thai Rak Thai" (Thais love Thais) Party, hereafter, TRT, fueled the general election campaign by promising to carry out a set of new schemes. One of the most eye-catching ones was the "30-Baht Health-care Scheme,"[1] hereafter, the "30-Baht Scheme" (US$1 = about 38-40 baht). During the election campaign, TRT indicated that the scheme would provide health care for everyone—regardless of the type or severity of the illness, at a cost of 30 baht, presumably per visit or per sickness. According to TRT's website, a health insurance premium of 100 baht per month per person would be collected to provide additional funding for the scheme to supplement the regular government budget.

After TRT acquired the majority vote and led the coalition government, the government put forward this scheme very quickly. Following a workshop in February 2001, the first pilot project was announced for implementation in six provinces beginning on April 1. The second pilot project in another 15 provinces followed in June. In October, the scheme was implemented country-wide, except for some inner regions of Bangkok, which were deferred until January 1 or April 1, 2002. Under the pilot and full-scale implementation, the proposed insurance premium was eliminated and the project has become solely a tax-financed program.

As a universal health-care coverage scheme ("UC" for short), the 30-Baht Scheme covers everyone who is not covered by other government-sponsored forms of insurance, i.e., the Civil Servant (and public enterprise workers') Medical Benefit Schemes (CSMBS), the Social Security Scheme (SSS), the Health Card Scheme, and the Health Welfare for the Poor and the Disadvantaged Scheme (HWPDS). In practice, the latter two schemes were converted to the 30-Baht Scheme. In fact, the way these two schemes were implemented became the foundation of the 30-Baht Scheme.[2]

Besides providing health coverage to persons who were not in the CSMBS or SSS, during its first year of implementation the 30-Baht Scheme was an attempt to reform the health-care financing system; it was aimed at shifting the paradigm that governs the health-service system to place the main emphasis on health promotion and disease prevention.

This paper is an early attempt to assess the consequences and impacts of this new scheme on the poor. The results provided in this report draw from both desk and field research. The desk research focuses on the implementation and impacts of the previous programs, and attempts to estimate changes in the financial burden of the poor as well as the incidence of poverty. The field research comprises two rounds of fieldwork that attempts to explore health-seeking behaviors of the low-income group prior to and after the new scheme was implemented. The first round of fieldwork was undertaken by 10 researchers who stayed for two months in 10 villages/communities in late 2001.[3] However, the main fieldwork results presented in this paper are drawn from the fieldwork led by the authors in seven provinces in 2003.[4]

II. IMPACTS ON THE USERS AND THE POOR

Although the 30-Baht Scheme preaches the concept of "universal coverage" and "entitlement/rights to health care"—as opposed to being a "welfare program"[5]—throughout the years that the TRT government has been in power, it has sent mixed messages to the public and health professionals. At

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times, the scheme was referred to as a "pro-poor program" where the high-income and middle class were persuaded to seek health services elsewhere so that they would not draw too much of the tight resources from the scheme. However, when a large faction in the Senate attempted to modify the National Health Insurance Act (which had been drafted to be the basis of the Scheme) to designate the Scheme as "for the poor/uninsured only," the government turned to claim that the law was indeed intended for all Thai citizens. Nevertheless, the prime minister later asked the Thai people to be patient with the Scheme—which might still have been "unsatisfactory" for the middle class, claiming that it had successfully assisted the poor thus far.

The impacts of this Scheme on the users, with special reference to the poor, can be categorized in four aspects as follows:

a) Rights and Access to Care

Since 1975, the low income group was supposed to be eligible for free health care. Before the 30-Baht Scheme, all the poor were theoretically covered by the HWPDS, which provided the "Low-Income Card" (LIC) to a single person who earned less than 2,000 baht ($50) per month or a family that earned less than 2,800 baht ($70) per month.[6] However, many studies consistently found that most of the low-income families did not receive the LIC and the majority of the cards were distributed to people or families that earned more than permitted under the eligibility criteria. (See the authors' review of these studies in Viroj and Anchana 2002a, which also indicates that the mis-targeted portions appear to have increased over time.)

Because of the mis-targeting problem, a significant number of the poor ended up buying the 500-baht ($12) health insurance card designated to provide year-round insurance for a family of up to five. According to the Socio-economic Survey (SES) administered by the National Statistical Office (NSO) in 2000, almost one-half (47%) of the poor had the 500-baht health insurance card, more than twice the number of the poor that received the LIC (21%) (Viroj and Anchana 2002a). Although these figures may include mixed up or misidentified cases, the figures do indicate that mis-targeting had been wide-spread.

By its design and coupled with the publicity which makes its presence known to almost everyone, the 30-Baht Scheme effectively eliminates the major part of the mis-targeting problem—the quota allocation and the information problems—which were rampant before the Scheme was implemented. Under the Scheme, steps were taken to solve the eligibility problems of Thai-national migrant workers who in the past usually had been unable to pass many bureaucratic constraints. Currently, the number of non-eligible persons (who include those who do not have Thai nationality) is down from about 5 million (in 2001) to about 2 million.

It turns out, therefore, that a supposedly non-targeting scheme such as the 30-Baht Scheme has helped many low-income persons to gain access to low-cost health care that they were supposed to have gotten years ago but did not, or had to pay an extra premium for such access (i.e., by buying the health insurance card). It should also be noted that having an LIC would not necessarily ensure access to health care or coverage. Before the 30-Baht Scheme was implemented, some residents in an urban slum in a northeastern province of Thailand who had LIC cards reportedly avoided seeking health-care services from the hospital listed on the card, as they felt that they were not welcomed there. They were also unsure about the benefits that the cards would provide, or whether a particular service would be covered by the card or not. The name of the card, which could be literally translated "health welfare for people with a low-income and for people who should be assisted," was rather ambiguous and not very informative. The LIC cardholders' experiences from various provinces suggest that the manner in which these people were treated varied greatly, often on a case-by-case basis depending on the personnel who handled their case. Some patients felt that they were not welcome—or even verbally harassed—by certain hospital officials,[7] but were treated very nicely by others on different occasions. During the admission of one of her daughters in a regional hospital, an LIC cardholder, who was eligible for free care, in a province in central Thailand, was always asked by hospital personnel to pay for the prescribed medicine from the hospital pharmacy, even though the attending physician told her that she did not have to pay. Finally, a nurse persuaded the hospital welfare officials to give the woman an "exemption." Under the new Scheme, uncertainties about rights and coverage appear to have diminished greatly, as the new scheme has been well advertised and thus is well known among the general public (and probably better known among the health-care providers as well).[8] In this connection, a large number of patients feel that they were treated better after the 30-Baht Scheme had been put in place.[9]

b) Health-seeking Behaviors

It is not uncommon to predict that, with a UC scheme in place, people would seek more of the free or low-cost health care since UC would remove the financial burden that is usually associated with seeking health care. Therefore, it had been expected that some people who had become eligible for this new scheme would visit health-care facilities more often than they had in the past. The figures released by the Ministry of Public Health (MoPH) indicated that, in fiscal year 2002, the number of outpatients who paid visits to its hospitals, which are supposed to look after more than 90 percent of the people in the 30-Baht Scheme, increased by about 54 percent over that of fiscal year 2001. The

number of inpatients has also increased, but at much smaller rates (about 7.5%), as they are partly constrained by the number of beds available in the hospitals.[10]

A large number of health-care providers in public hospitals claim that patients have flooded into their hospitals after the introduction of the 30-Baht Scheme. Some of the health-care providers observed that a number of people seek health services earlier than they had in the past. According to them, some people seek services for health concerns that could easily have been taken care of by themselves. Another claim, albeit less frequently voiced, by some providers is that people now take less care of themselves (i.e., a moral hazard problem has arisen as a result of the new health insurance scheme).

While it is agreeable that more patients now seek health services earlier than they had in the past, it is not clear whether such actions are appropriate or not. There has been no systematic study on this issue. However, a team of senior medical professors—heading by Prof. Charas Suwanwela, a former dean of the Faculty of Medicine, Chulalongkorn University—paid several visits to a number of hospitals in rural areas at the early stage of the Scheme's implementation, and found that almost all patients who sought health-care services did have reasonably alarming reasons to seek care from the providers.

Our findings from the field, which are based on information gathered from various focus group discussions and interviews with people from various income groups in several provinces in three regions of Thailand, include the following:

- Some patients agree that *some* hospitals have become more crowded after the 30-Baht Scheme was put in place;
- Most people indicate that their health-seeking behaviors have not changed. They usually assess their illness and take action accordingly. In an urban area where there are drugstores nearby, patients with a mild illness (based on their own assessment) would buy medicines from the drugstores (or grocery stores, for common drugs), as it would be cheaper and less time-consuming than going to a hospital or clinic. In rural areas where there are no nearby drugstores, many would go to a sub-district health center instead. Only when they believe that the illness is out of hand would they go to the hospital or go to see a doctor at a clinic. Choosing whether to go to a hospital or a clinic would depend on their income and time available (elderly people are more likely to use public services), how urgent the patient feels s/he needs to see a doctor (many rural dwellers would choose to go to a private clinic when they feel that their situation is urgent,[11] or when it is more difficult to assess the situation, e.g., when a child is ill). In an emergency case, however, most would go to a hospital right away. People from a low-income family tend to go to their designated hospital,[12] and hope that the hospital would refer them to a larger hospital if needed. However, a better-off family in a peri-urban area would send the patient to the provincial hospital right away, or even to a private hospital, especially during nighttime or on the weekend when most public hospitals would be understaffed with doctors;
- Almost every patient indicated that, *when possible, they would stay away from hospitals as much as they could*. Many were amazed at the notion that someone would be willing to seek more or *unnecessary* care just because the 30-Baht Scheme had been put in place. According to them, the only difference after the introduction of the 30-Baht Scheme has been that, *some* patients would *occasionally* switch from going to a private clinic/hospital to use the public hospital instead. Even for these patients, at times they found that the hospital was too crowded and decided to waive their rights, so that they could get into a shorter waiting-line to see the doctor;[13, 14]
- In this connection, a number of dwellers in two low-income communities in Bangkok complained that they had several bad experiences with treatments received at a private hospital that participated in the 30-Baht Scheme. According to the villagers, they insisted that they would rather buy some medicine at a nearby drugstore than go to the hospital 4-5 kilometers away if they did not think that their illness was severe. However, when they eventually decided to go to the hospital, the screening doctors there did not take their illnesses seriously, and asked them to go home after giving them some common drugs (paracetamol and other such drugs). In one case, a patient urged her relatives to bring her to another private hospital and was told that she came too late; she died shortly after at the second hospital. Another case resulted in a ruptured appendix. Yet, another person from this community also had to pay multiple visits to this hospital before she was admitted to the ICU on the third visit, as her illness had become apparently severe. Only after that did she get fairly good treatment and follow-up service that satisfied both the patient and her relatives. Although some cases are in a gray area, such as appendicitis which a lot of even experienced doctors could misdiagnose, the three mishaps experienced by a small cluster

in the community suggest that, at least in some areas (and maybe because of some relationship with some of the private hospitals in the Scheme), the moral hazard from the hospital side might even be more problematic than the moral hazard from the patients;[15]

- However, even though most patients like to think that they would go to the hospital only as a last resort (after self-assessment and self-care by buying medicines from a nearby drugstore), people do have different attitudes or thresholds on the "severity" of an illness, which appear to vary from one person to another. (The most general conclusion that we could make out of several focus group discussions is that a male's threshold is usually higher than that of a female's.)[16] Therefore, even after self-assessment, there would still be a significant number of cases going to the hospital that would be regarded by the health-care providers as non-severe, or not urgent, or even not worth a visit to a doctor;
- When compared with the time before the implementation of the 30-Baht Scheme, the health-seeking behaviors of the low-income group had not changed very much (probably their behavioral changes are much less than those of other income groups). Part of the reasons are:
  - Limited alternatives. Most users are assigned to the same hospital to which they used to be assigned under the LIC or the 500-Baht Health Card Scheme. If they go to another hospital, they themselves would have to pay. In addition, transportation costs are still a barrier in many rural areas where public transportation is lacking. Therefore, even when they do not have much confidence in the designated hospitals, they usually go there and leave it to the hospital personnel to choose whether or not to refer them to a larger hospital;
  - Some poor people in remote areas still consider the 30-Baht co-payment expensive. To them this new Scheme does not come with a lower price tag, as commonly viewed by others.

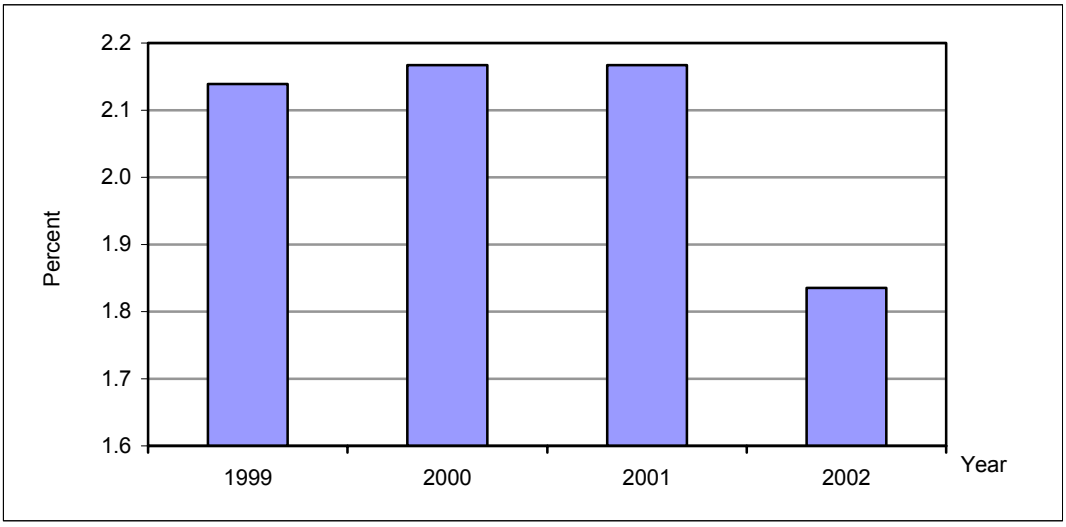
c) Financial Burden

The 30-Baht Scheme was intended to remove financial burdens connected with health care, in that illness can be unanticipated and the cost concerned might be unpredictable. This study provides preliminary estimates on the effects of the 30-Baht Scheme and the universal health coverage program on households' cost savings and on poverty reduction. The estimates employed data mainly from the nationwide SES. Based on the stylized fact that the share of total health expenditure as a proportion of GDP in Thailand has been rather stable, we estimated the households' cost savings, based on the decremental shares of the households' health expenditure vis-à-vis total income and expenditures, and attributed them to government intervention (see Figure 1). The estimated implied cost savings of households in 2002 (relative to the shares of their health expenditure in the years 1999 and 2000) range from 7 billion to 8 billion baht, which is comparable to the incremental health budget the government added in fiscal year 2002, the first year that 30-Baht Scheme was implemented nationwide (except for inner Bangkok).[17]

In terms of poverty reduction, the study compares over time the percentage of people who were impoverished because of health-care expenses, using data from SES. The figures were drawn from the households that had a per capita income above the poverty line, but had after-health-care income (gross income after subtracting the household's health expenditure) that fell below the poverty line. We found that the percentage of these impoverished groups declined from 2.15 percent of total households in 1992 to 1.84 percent and 1.53 percent in 1994 and 1996, to 1.1 percent and 1.3 percent in 1998 and 2000, respectively, and to 0.7 percent in 2002. The early declines could be attributed to the expansion of the Health Welfare Program for the Low-Income Group to cover elderly people and children in 1994, and its subsequent financing reform toward per capita budgeting that took place between 1998 and 2000. The decrease in 2002 is most likely the result of the 30-Baht Scheme (plus a small effect from the expansion of coverage of the Social Security System in mid-2002). Based on these figures, the households that were impoverished because of health-care burdens decreased by two-thirds as a result of the expansion of coverage toward universal coverage. The above finding is similar for all regions, but is more pronounced in rural areas.

We also measured the number of households that became impoverished because some members were hospitalized. We found, however, that the number of this type of household is rather small—ranging from one-seventh to one-fourth of those who were impoverished because of health expenses. This finding suggests that a comprehensive universal coverage scheme that also covers major outpatient expenses would still be crucial if poverty reduction is considered to be one of the main objectives of the universal health coverage program in Thailand.

Figure 1 Percentage of Health Expenditure to Household Income



Source: Viroj NaRanong et al. 2005a (processed from the NSO Socio-economic Survey).

On the qualitative side, our findings on this issue are as follows:

- For most people, including those in the low-income group, their financial costs for health care have not changed drastically after the implementation of the 30-Baht Scheme. Many families only had to change the method of payment from 500 baht per year (per family of five or fewer) to pay 30 baht per visit. This change could result in more or less financial costs, usually depending on whether or not that family had a member with a chronic disease. However, even when taking that into account, not many people regarded the financial burden to be the most important issue, as most of them felt that they could afford to pay 100-200 baht for a visit to a clinic when needed. The exception is the low-income group who clearly preferred to pay 30 baht per visit rather than a lump-sum advanced payment of 500 baht. They were the only group concerned when asked a hypothetical question about whether their health-seeking behavior would be changed if the government were to raise the co-payment from 30 to 50 baht. It is difficult for these people to pay a lump sum of 500 baht, which they considered a large amount. Some also complained that the subdistrict health centers had already raised their fee from a variable fee (most of which was in the range of 15-20 baht for common illness) to a flat fee of 30 baht.
- However, although many felt that the Scheme did not have a direct impact on the financial burdens they faced, most people at all income levels preferred to retain this Scheme (or a similar scheme such as the 500-Baht Health Insurance Card) rather than returning to a targeting program like that of the LIC scheme. The main reason provided during our focus groups/interviews was that, while most of them could afford to pay 100-200 baht per visit occasionally, or could, at times, afford to be an inpatient in a private hospital, a time could come when they would need to be admitted to a hospital and they would be unable to pay on their own. When that time comes, this scheme would be the last resort, ensuring that they would still get some care without having their family impoverished. Interestingly, many who used to buy the 500-Baht Health Card also cited the same reason for buying such a card, even though they felt that every one in their families was rather healthy and would unlikely need to use the services covered by that scheme.

d) Quality of Service

One concern in implementing the 30-Baht Scheme is the quality of health care. However, it is rather difficult to assess the quality of the medical service—or even overall service. This section, therefore, gathers only the users' perception on quality issues.

- Unlike when the 500-Baht Insurance Card was implemented, when many interviewees perceived that some improvements had been made in the service they received, not many

interviewees attributed this element to be the outcome of the 30-Baht Scheme. Some patients who actually got the services—most of which were delivered in the outpatient department—felt that the hospitals tended to use more "common" medicines (such as paracetamol/acetaminophen) than in the past, which was a different situation compared with times when they went to see the same doctors at their clinics. However, virtually none of them perceived any clear deterioration in the services. While a significant number of patients did not like the system that required them to go to the designated hospital first, some patients perceived some improvements in the referral system.

- Most of the high-income group, who were accustomed to using services from large and private hospitals, were not very satisfied with the 30-Baht Scheme, partly because of the rationing of care. A number of interviewees experienced slower service when they used the 30-Baht card, especially in hospitals that have separate queues for the patients using the 30-Baht Scheme and those who self-pay.

III. EXPECTATION OF THE USERS AND THE POOR

An indirect method we used in order to evaluate whether the 30-Baht Scheme has fulfilled the void or the needs of users and the poor was asking the interviewers and those who participated in our focus groups to rank the four most important things that they expected from the health-service system. The choices that were provided by the researchers are as follows: (a) a universal coverage scheme like the 30-Baht Scheme or other low-fee health-care schemes, (b) a health-service system with a sufficient number of hospitals and personnel, (c) the right to choose the health-care facilities, and (d) receiving good treatment (medically and verbally) from the health-care personnel. During the interviews/focus group discussions, the participants were also allowed to add their own suggestions to these four items.

In our interviews/focus groups, most participants ranked item (b) "a health-service system with a sufficient number of hospitals and personnel" as the most important thing that they would like to have, with some exceptions from some participants from the low-income group who chose item (a) "a universal coverage scheme like the 30-Baht Scheme or other low-fee health-care schemes" over item (b). Only a small proportion of the subjects chose (c) or (d) as their first priority.

The second choice showed more variation than the first one. Most respondents who chose item (b) as their first choice tended to choose item (a) as their second choice, and vice versa. However, some respondents ranked item (d) "receiving good treatment (medically and verbally) from the health-care personnel" as their second priority. A smaller number of respondents chose item (c) "the right to choose the health-care facilities" as their second priority. Interestingly, many Village Health Volunteers who also act as intermediaries between the MoPH and the villagers and should have a better understand about the health-care service and referral systems tended to give a high priority to item (c) "the right to choose the health-care facilities." This might reflect their awareness of the limitations of the existing health-care service and referral systems.

In light of these answers, we may conclude that people are more concerned about the inadequacies of hospitals and personnel (especially doctors) than the free or low-cost insurance program that the 30-Baht Scheme is intended to provide. A caveat to that conclusion is that these responses have been made after the 30-Baht Scheme has already been implemented and might have swayed many people's opinion to another area that is lacking and that still has not been addressed as well as the health insurance issue.

IV. CONCLUDING REMARKS

The 30-Baht Scheme is aimed at providing *universal health-care coverage/insurance* for everyone who is not currently covered by two other government-sponsored insurance programs (i.e., CSMBS and SSS).

While the 30-Baht Scheme preaches the concept of "universal coverage," it has also advertised itself as a "pro-poor program" that is aimed at lifting the financial burdens arising from health–care costs, which could be detrimental, especially for the poor. According to the data from the national SES, the scheme appears to be successful in reducing poverty, probably much more than other targeted schemes in the past that often let the poor "fall through" the selection process (such as in the LIC Scheme). The more systematic and universal approach of the 30-Baht Scheme, which recognizes the "entitlement/right to health care" of everyone, makes the poor less vulnerable to being shut out from accessing the health-care system and makes them less subject to the whims of health providers in showing kindness.

Although the number of people who seek health care has increased substantially following the implementation of the 30-Baht Scheme, our fieldwork suggests that the health-seeking behaviors of the poor have not changed much after the Scheme started, as most of them have rather limited choices. For most people, including the low-income group, the financial costs for health care did not change drastically after the implementation of the 30-Baht Scheme.[18] However, most people feel more secure with this Scheme in place, as they now have an insurance against a drastic or catastrophic illness that they could suffer in the future.

While almost all beneficiaries—especially the poor—welcome this scheme, most people voiced concern about the inadequacies of hospitals and health personnel (especially doctors in small public hospitals), which is the main problem that the government needs to address should it really aim at providing universal and equal access to good quality health care for all, especially for the poor.

ENDNOTES

[1] The exact translation would be the "30 baht for curing every disease" scheme. About a year ago, the official name of the scheme was changed to "30 baht [to] help Thai people stay away from diseases."

[2] The payment mechanism of the 30-Baht Scheme was also influenced by SSS as well.

[3] These researchers work under the Poverty Reduction Partnership (Phase II) between theWorld Bank and Thailand Development Research Institute (TDRI 2003).

[4] See Anchana NaRanong (2005), which is part of TDRI's Monitoring and Evaluation of Universal Health Care Coverage in Thailand, 2nd Phase, 2003-04.

[5] In the sense that is commonly used in the United States.

[6] These criteria were in effect since 1994. In 2001, the official poverty line was about 700-800 baht ($175-200) per person per month.

[7] One LIC cardholder in the Central Region recalled an episode that, when she bought some food and brought it to eat in the hospital, she was questioned how come she had money to buy food while had no money to pay for her daughter's medicine. Another LIC in the Northeastern Region told the researcher the reason why she also bought the 500-Baht Health Insurance Card: "I went to the hospital with a neighbor who had the 500-Baht Card, and I was told to sit on the floor while she got a seat. So I decided right then that I needed to save money to buy this card."

[8] There are still some gray areas on the benefit package and these have occasionally caused problems, e.g., an exclusive clause which states that the scheme would not cover the cost of medicines that are not on the Essential Drug List. Some hospitals also try to cut their costs by cutting down on the number of drugs on their hospital drug list.

[9] However, part of such an improvement could be the result of more scrutiny from both the Ministry of Public Health (MoPH) and the public. This has forced the providers to be more conscious (or careful) about their service. Yet, this does not come without a cost, as many health-care providers have complained about their work after the implementation of the Scheme and are less satisfied with their job. Many cited this as the reason that nudged them to decide to resign from public hospitals.

[10] Both figures are from Viroj NaRanong et al. 2005b. Although figures released by various sources may differ from the above, as there were also changes in the definition of outpatient visits (see also discussion of data inconsistencies in Viroj NaRanong et al. 2005b), there is a virtual consensus throughout the country that more patients than previously are using the health-care services in most of the MoPH hospitals.

[11] Although the patients realize that most clinics do not have facilities as good as hospitals, at a clinic they would be able to see a doctor right away, and, if needed, the doctor would be able to send or refer them to an appropriate medical channel without having to wait for a long time as would be the case when they go to the hospital on their own.

[12] Before the introduction of the 30-Baht Scheme, most people in this income group also had the LIC or 500-Baht Health-Insurance Card, both of which designated a gatekeeper hospital that each cardholder would be authorized to visit. Therefore, in this respect, their choices were not altered much after those two programs were replaced by the 30-Baht Scheme.

[13] Not every hospital applies different waiting lines for patients with different types of eligibility (or for paying versus non-paying patients).

[14] To cross-check the results of our study, which is mainly qualitative, the second author has supervised three graduate research projects that use similar questionnaires that focus on issues discussed in this paper in three provinces. One preliminary result from a province in the Central Region indicates that some patients (less than 5%) go to the health-care facilities to get medicines or vitamins while they were not sick. Some of these cases may happen when the people accompany the patients to the health-care facilities. Also, these incidents tend to take place at sub-district Health Care Centers, which usually have very short waiting lines.

[15] Some workers in the SSS also claim that many doctors would not listen to them or examine them seriously. They speculate that not only are financial issues involved, but also that the screening doctors are accustomed to frequent visits by healthy workers who just visit them to get a physician's note that they could use to apply for sick-leave from their companies. Therefore, some of these doctors would presume that most patients were not ill. Some SSS

patients also indicated that, only after they get pass the "gatekeeper" to a specialist or are admitted as an inpatient, would they be treated normally like other patients.

[16] Another pattern, although slightly less common, is that, when controlled by age group, the younger generation's threshold tends to be lower than that of the older generation, many of whom are also less familiar with the hospitals and often try harder to avoid going there as well.

[17] Based on the same approach, we find that the estimated cost savings of households in 2002 (relative to the years 1986 and 1988) range from 27 billion to 51 billion baht. These figures are considered lower estimates of household cost savings from the universal health coverage program, since the 1980s had already seen the implementation of CSMBS and the Health Welfare Program for the Low-Income Group.

[18] Except, however, for some families that have a seriously ill member (or one with a chronic disease) who received a specific treatment/operation as the result of the 30-Baht Scheme.

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Facilitating the Entry of New Generic Drugs: A Proposal for Thailand

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Thai people are suffering from the high prices charged for brand-name drugs at a time when per capita drug consumption is unprecedentedly high. Per capita drug consumption in 2004 was slightly over 958 baht, an increase of 66 percent over that of 2000.[1] Generic drugs, which cost less than brand-name drugs and are therefore more competitive, play a significant role in increasing access to drugs and reducing the expenditure on them. However, Thai generic drug producers face several important barriers to enter the market: for example, ambiguity concerning the patent status of brand-name drugs, and inadequate research skills and funds to conduct a bioequivalence study. In this article, we offer a proposal to clarify the doubtful status of patents and to provide incentives for generic drug producers to seek market approval for their new drugs. Considering the level of development of the Thai economy and Thai generic producers, we propose an amendment of the Patent Act 1999, the Thailand New Drug Application (TNDA) and the Thailand Abbreviated New Drug Application (TANDA) to facilitate timely entry of generic drugs on the market.

The absence or delay in the entry of certain generic drugs, such as AIDS drugs, could jeopardize the health of Thai people. In addition, Jiraporn (2005) estimates that, on average, a one-year delay in the entry of one generic drug causes an increase in drug expenditure ranging from 4.29 million to 43.95 million baht. The increase in drug expenditure is due to a lack of access to cheaper drugs. There are two important barriers to entry for a generic drug. The first comprises non-patent-related barriers, such as, the ability of generic producers, the cost of a bioequivalence study, the sufficiency of bioequivalence facilities, and the monopolies existing in the generic drug market.[2]

The second barrier is related to patents. A generic drug may be marketed only after relevant patents of a brand-name drug have expired. Drug development research is dynamic. New discoveries are possible from the basic stages of drug development to a clinical trial and even a post-clinical trail. Thus, relevant patents could be granted at different points in time both before and after the drug is approved to market, resulting in a risk of patent infringement at any time. Practically, it is not so easy to identify all the relevant patents. The generic producer needs to know all aspects of the brand-name drug so that it can find all the patents associated with all aspects of the brand-name drug. Moreover, to understand the information in the patent and to be able to match patents to an associated brand-name drug, it is necessary to have expertise in pharmacology and chemistry. Last but not least, the generic producers may not acquire the techniques, skills, and experiences necessary to effectively search relevant patents and monitor such new patents. However, even if they are equipped with sophisticated searching techniques, the generic producers still have a hard time in using the current patent database provided publicly by the Department of Intellectual Property (DIP), Ministry of Commerce.

Pharmaceutical multinational enterprises (MNEs) increasingly use multiple patents covering multiple attributes of a single drug, for example, active substance, derivatives of the active substance (such as polymorphs, isomers, and metabolites), formulations, use and process, in order to extend the terms of patent protection. The key method that MNEs producing brand-name drugs have for delaying generic entries—using patenting strategies—is to threaten a generic producer. They do this in order to stop any attempt by such a producer to market a generic drug; otherwise, the MNEs threaten, such a producer could face allegations of patent infringement. The expected reward from pursuing litigation is often less than the expected loss from such a

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course of action. Considering the high legal costs, the time-consuming litigation procedure, uncertainty about the court's decision, and the risk of paying a heavy fine if it loses the case, the generic drug producer is more likely to give up its attempt to market its generic drug. In the presence of ambiguity about the patent status of the brand-name drug, the MNE's patenting strategies become even more effective in delaying the entry of generic drugs.

This article focuses on the barriers related to ambiguity about patent status only. In general, we could facilitate the entry of new generic drugs by reducing the number of relevant patents, revealing all relevant patents, and giving an incentive for the generic companies to challenge unsuitable patents. We propose adding a separate clause about the patentability of pharmaceutical products to section 9 of the Thai Patent Act 1999 (the section covers what is not protected by the Patent Law) in a way similar to that done for the Indian Patents (Amendment) Act 2005, which explicitly states the unpatentable attributes of drugs. If the patent law were amended and then enacted in Thailand, there would not be many trivial secondary patents, which potentially cause delays in the entry of generic drugs. Moreover, we propose new processes for drug and generic drug application, similar to that of the United States New Drug Application (NDA) and Abbreviated New Drug Application (ANDA) respectively. The proposed application processes would require a brand-name company to provide ANDA applicants with relevant patents of a brand-name drug, and award six months of exclusive marketing rights to the first generic company that markets a drug after winning a patent lawsuit against a brand-name drug.

The article is organized as follows: section I provides a brief overview of the structure of the Thai pharmaceutical market. Section II reviews the effect of competition from generic drugs. Section III analyzes patent-related barriers to entry. Section IV discusses practices of extending exclusive monopoly rights in Thailand. Section V provides a proposal to facilitate generic drug entry. Finally, section VI is the conclusion.

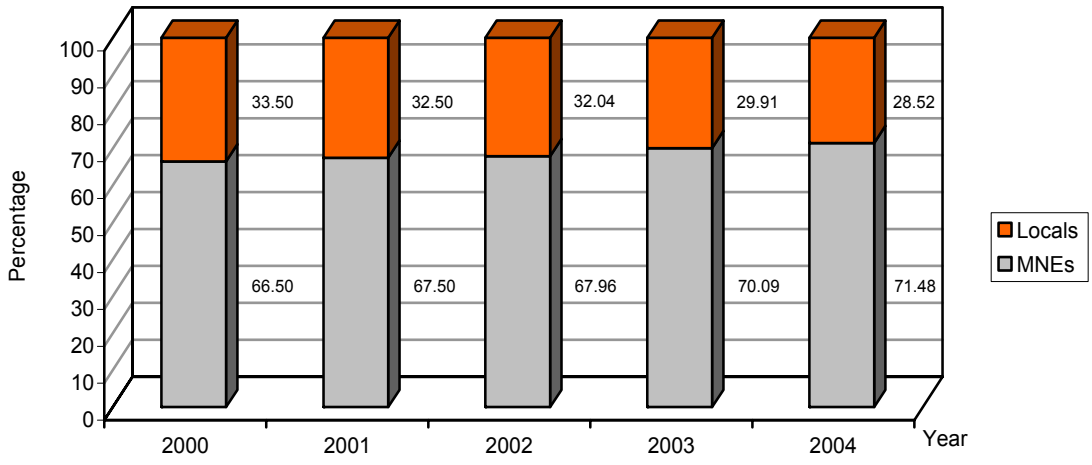
I. THE STRUCTURE OF THAI PHARMACEUTICAL MARKET

The Thai pharmaceutical market has grown considerably. As shown in Figure 1, in 2004, the market had a value of 53,102 million baht, an increase of 64 percent from that of 2000. MNEs play an increasingly significant role in the market. The market share of MNEs has grown at the expense of local producers. In 2004, more than 70 percent of the market share belonged to MNEs, while less than 30 percent of market share belonged to local producers. Most of MNEs' products are brand-name drugs; the majority of sales of brand-name drugs come from off-patent brand-name drugs. In contrast to MNEs, local producers produce mostly generic drugs, which are significantly cheaper than brand-name drugs.

II. PRICE EFFECT OF COMPETITION FROM GENERIC DRUGS

Unlike brand-name drug producers, generic drug producers do not go through a long and costly process of drug development, so they can set the price of a generic drug much lower than the price of a brand-name drug. To give an idea how expensive brand-name drugs are compared with generic drugs, using the data on the

Figure 1 Market Share of MNEs and Local Producers



Note: The sales estimates represent direct and indirect purchases by retail pharmacies from pharmaceutical wholesalers and manufacturers.

Source: Intercontinental Marketing Services (IMS).

expenditure of various AIDS drug formulations in Jiraporn et al. (2004), we find that the average price of generic drugs sold in Thailand in 2004 is only 31 percent that of the average price of brand-name drugs. Lower-priced generic drugs clearly increase access to medicines for low-income and middle-income consumers. While a literature search showed no systematic study of the price effect from generic drug competition in Thailand, such a review on the effects of competition from generic drugs in other countries could provide a better understanding of the issue and serve as a good reference for the Thai pharmaceutical market.

Empirically, the effects of competition from generic drugs are mixed. Caves et al. (1991) studied the price effect of competition between generic drugs and brand-name drugs that became off-patent drugs in the United States from 1976 to 1987. They found that the average price of brand-name drugs drops 2 percent after the first generic drug enters the market. Moreover, the average price of brand-name drugs decreases by 22 percent if there are 20 generic drug competitors. Frank and Salkever (1997) studied 32 brand-name drugs that lost patent protection in the United States during the period 1984-1987. They found that competition from generic drugs increase the price of brand-name drugs. The result is driven by lower elasticity of demand among brand-name drug consumers. Although competition from a generic drug may not always lead to a decrease in the price of a brand-name drug, the generic drug is a cheaper alternative that can substitute for a brand-name drug. Therefore, generic drugs increase people's access to medicine.

III. PATENT-RELATED BARRIERS TO ENTRY

A patent is an exclusive rights granted by the government to a patent holder to sell, distribute, produce, and/or import the product, subject to the patent for a period of 20 years. According to Article 5 of the Thai Patent Act 1999, an invention is patentable if it meets three requirements: novelty, non-obviousness, and industrial usefulness. The clock of protection starts ticking on the date of filing an application for a patent. However, pharmaceutical products can enter the market when granted marketing approval by the Food and Drug Administration (FDA). Thus, the effective period of protection starts from the marketing date and extends to the end of the patent life. After the expiration of relevant brand-name drug patents, a generic drug may enter the market.

As repeatedly claimed by pharmaceutical MNEs, the rationale of patent protection is to compensate pharmaceutical producers for their substantial research and development (R&D) costs and to provide an incentive for the production of innovate new and more effective drugs in the future.[3] It is noteworthy to discuss the validity of this claim. As argued by Angell (2005), there are convincing reasons to believe that the brand-name drug industry is overly protected by patents. Further, the claim about how innovative the industry is remains doubtful. First, most of the new brand-name drugs are not really innovative drugs.[4] In fact, many new drugs are "me-too" drugs that are versions of already marketed drugs and are no better than already marketed drugs in the same therapeutic class.[5] Second, quite often, the early stage of R&D of many important drugs, arguably the most important stage, is carried out by government agencies, universities, and biotechnology companies.[6] Moreover, some of the research is funded by taxes. Therefore, pharmaceutical companies get monopoly rights on drugs that are not truly innovative and have been partly funded by the public. Consequently, it should be clear that practices aiming to extend monopoly rights beyond the patent life are immoral and unfair.

Because the pharmaceutical market is lucrative, a brand-name producer would put a serious effort into extending its monopoly rights beyond the period of patent protection, using complex life-cycle management strategies. Life-cycle management includes strategies such as patenting strategies, a development over an existing drug (line extension), such as changing the dosage of a drug, changing the form of delivery, changing the formulation to add safety, or producing extended-release drugs, switching to over-the-counter (OTC) drugs, entering into manufacturing and distribution agreements, and pursuing marketing strategies to persuade consumers to switch to the new drug, a variant of the already marketed drug.[7] One strategy alone or a combination of the above-mentioned strategies could be used to successfully extend the monopoly period.

An "evergreening" patent is a widely used patenting strategy that prolongs the period of patent protection.[8] An evergreening patent is a strategy by which MNEs use multiple patents covering multiple characteristics of a single drug to extend the term of patent protection.[9] The patents could cover both primary patents and secondary patents that frequently have the potential to delay the entry of generic drugs.[10] While primary patents normally cover an active substance, a formulation, or a use, secondary patents normally cover a new form of a known substance, a new use of a known substance, or a new property of a known substance.[11] In practice, generic drug producers have to choose between waiting for the expiration of all relevant patents, or marketing the generic version of the drug and facing the risk of patent infringement litigation and its associated costs. Under certain conditions, an evergreening patent effectively blocks the entry of generic drugs, because it is impossible for generic producers to avoid patent infringement. There are many case studies of evergreening patents and other life-cycle management strategies. Two of the best known cases in the United States are perhaps the Nexium and the Claritin cases.

First, produced by AstraZeneca, Nexium, a brand-name drug used to cure heartburn, is a good study case of how drug companies use life-cycle management to successfully extend the monopoly period of a previous version of the drug, in this case, Prilosec.[12] According to Angell (2005), Prilosec is a mixture of an active and a possibly inactive form (isomers) of the Omeprazole molecule. When Prilosec's patent protection was going to expire in 2001, AstraZeneca was granted a patent on the active form of the Prilosec molecule.[13] Under the protection of the new patent, AstraZeneca marketed the presumably new product under the name Nexium (in fact, the only new feature is its color, purple). In other words, despite the color, Nexium is equivalent to Prilosec. After receiving marketing approval, AstraZeneca put on one of the most massive marketing campaigns ever conducted to persuade consumers to switch to Nexium. In addition, AstraZeneca made Prilosec an OTC drug and got three years of exclusivity, resulting in larger aggregate sales (including Prilosec and Nexium) in 2002 compared with 2000 when sales of Prilosec reached their peak. Unfortunately, the success of AstraZeneca's strategies comes at the expense of consumers and generic drug producers.

Second, Schering-Plough used a brand-name drug for treating allergies, Clarinex, to extend the monopoly period of its previous version of the drug, Claritin.[14] Just before the patents on Clarinex expired in 2002, Schering-Plough patented the active metabolite of Claritin and marketed it as Claritin. A metabolite is the chemical compound into which a patient's body metabolizes or converts the active ingredient of a drug. In other words, the active ingredient in Clarinex is the molecule into which the body converts Claritin. Therefore, Claritin is equivalent to its previous version, Clarinex. In theory, only patients can directly infringe a metabolite patent by swallowing the drug and then metabolizing it into the claimed molecule. Nevertheless, the metabolite is troublesome to generic producers because the patentee normally sues the generic producers for inducing the infringement by selling the drug. Schering-Plough also made Claritin an OTC drug and undertook a massive marketing and advertising campaign. Unlike Prilosec, Schering-Plough did not get three years of exclusivity for its OTC Claritin, and it has been less successful with Clarinex compared with AstraZeneca's product Nexium.

IV. PRACTICE OF EXTENDING EXCLUSIVE MONOPOLY RIGHTS IN THAILAND

The problems with the practice of extending patent protection are widely acknowledged by governments and anti-trust agencies in many countries, for example, the United States, Canada, India, and Thailand. In Thailand, there is evidence that the practice of extending a patent's term is widely used. Jiraporn et al. (2004) detected a number of suspicious patents claiming new uses for off-patent drugs, combinations of off-patent drugs and soon to be off-patent drugs, or a combination of off-patent drugs, and a new dose (for instance, from three times a day to two times a day). To further explore the issue, we examine the relevant patents of Pilosec, Nexium, Clarinex, and Claritin in Thailand to see whether there is evidence of suspicious patenting practices, which could delay the entry of generic drugs.

We looked up the relevant patents of Nexium and Losec, as mentioned previously a commercial name for Prilosec in Thailand, in the Thai FDA drug patent database, arguably the most complete database available in Thailand. We could not find any patents on Nexium (its generic name is Esomeprazole). Ranked 18th in sales in Thailand in 1999, Losec (its generic name is Omeprazole) has four relevant patents with expiration dates ranging from December 2017 to November 2018.[15] However, owing to the incompleteness of the data used to construct the database, it is possible that there might be other relevant patents that remain unrecognized or unidentified by the creator of the database. Nonetheless, we suspect that the latest granted patent claiming a new crystralline form of OmeprazoLe (a polymorph of Omeprozole) could delay the entry of generics.[16] In theory, under certain conditions, a polymorph is therapeutically equivalent to an active substance and thus is not truly novel. In many cases, it is obvious to other people in the field of interest. In practical terms, the presence of the polymorph patent forces generic producers to choose between entering the market, regardless of the patent, and accepting the risk of time-consuming legal processes and uncertain court decisions, or waiting until the polymorph patent expires. Therefore, the patent possibly adds one more year of patent protection to Losec.

Using the Thai FDA drug patent database, we found one patent for each drug, Clarinex (its generic name is Desloratadine) and Claritin (its generic name is Descarboethoxy Loratadine). Clarinex's patent will expire in February 2018, and Claritin's patent will expire in December 2020. Although it is beyond our ability to verify how the two patents differ from each other, it appears that the Clarinex patent is not for a metabolite of the active molecule in Claritin.[17] In fact, the Claritin patent claims extended release of the oral dosage composition.

Other than the above-mentioned drugs, we also found three more drugs with multiple patents, as follows: Zoloft (its generic name is Sertarine), produced by Pfizer, has five patent applications with different expiration dates, ranging from June 2018 to October 2019.[18] All of Zoloft's patents are pending. Taxol (its generic name is Paciitaxel), produced by Bristol-Myers Squibb, has four patent applications with various expiration dates, ranging from March 2016 to March

2002.[19] All of Taxol's patents are pending. In addition, we found two patents associated with Augmentine (its generic name is Amoxycillin and Clavalanic acid).[20] One patent is in the process of examination and will expire in July 2012, if it is actually granted. Another one has been granted and is scheduled to expire in April 2015. As mentioned above, the database is incomplete and should be used with caution. It is possible that there might be other relevant patents but unrecognized or unidentified by the creators of the database. These multiple patenting practices are suspicious and possibly delay generic drug entries. DIP must scrutinize those applications and further relevant applications in order to avoid the possibility of delaying the entry of generic drugs. Considering resources of that Department, the ability of the government to screen suspicious patents effectively remains in doubt.

The brand-name drug company's key to success in using patenting strategies is to threaten the generic drug producer so that it would stop any attempt to market the generic drug; otherwise, the generic drug producer could face allegations of patent infringement. The expected reward of becoming involved in litigation is often less than the expected loss. Considering the high legal costs, the time-consuming litigation procedures, uncertainty about the court's decision, and the risk of having to pay a heavy fine if the generic drug producer loses, that producer is more likely to give up its attempt to market its generic drug. In Thailand, the patenting strategies are likely to effectively extend the exclusivity period of the brand-name drug due to two factors.

First, the enforcement of Article 5 of the Thai Patent Law is weak, particularly with regard to the aspects of novelty and non-obviousness. Proving the novelty and the non-obviousness of the drug patent requires extensive knowledge of pharmacology and chemistry. Obviously, DIP does not have sufficient resources and ability to scrutinize or even understand complicated drug patent applications, let alone the ability to recognize secondary patents. Instead of cooperating with experts from FDA or universities, the Department has chosen to keep the task to itself. Sometimes, it makes a decision based on the decisions made by the intellectual property rights (IPR) agencies in developed countries, particularly in the United States and European countries, where the enforcement of IPR appears to be as lenient as anywhere else in the world, except in India. Therefore, it is no surprise that many secondary patents have been granted that are not truly novel and non-obvious. Under certain conditions, these secondary patents could effectively block the entry of generic drugs. Unfortunately, this experience will persist as long as there is no serious attempt to strictly enforce the Patent Law and increase the quality and quantity of human resources in the aforementioned Department.

Second, in reality, it is very difficult to detect all the relevant patents of a brand-name drug, particularly secondary patents, which often are not obvious, or even trivial improvements or characteristics of a known drug. The generic producers' ability to detect all relevant patents is tremendously lessened due to the ambiguity about the status of a brand-name drug's patent, which is partly caused by the drawbacks in Thai drug patent databases. Using the current databases, it is extremely difficult for generic producers to plan the development of new generic drugs. They would not know when the targeted brand-name drugs could be imitated legally, when to start conducting research on new generic drug development, or when to market the generic drugs.

There are three sources of drug patent information in Thailand. Each of them has advantages and disadvantages. Unfortunately, none of them is truly beneficial to the generic producers. First, the official database provided by DIP is the most comprehensive patent database in Thailand.[21] There are various useful keyword options, for example, International Patent Classification code (IPC), claims, application number, patent number, inventor's name, applicant's name, and title of invention. Despite being an official and the most important patent database in the country, the database website is difficult to access owing to server problems. It is not user-friendly, at least with regard to searching for drug patents. Almost all keywords must be Thai letters, which frequently causes confusion and inconvenience because there are multiple ways of spelling the Thai version of English-language words.[22] More importantly, it is not useful for searching a drug patent simply because one cannot directly search by using convenient keywords such as a generic name or a brand name (trade name).

The second database is the drug patent database available on the FDA website.[23] Constructed by knowledgeable pharmacists and patent law experts, it apparently is the most sound drug patent database in Thailand, and can be easily searched through convenient keywords such as generic name and brand name (trade name), and therapeutic group. Nonetheless, the database has some important drawbacks.

First, the database entries cover the period from 1992 to 2004 only. Therefore, it leaves out patents that expired before 2006. Second, the database was constructed by using all available drug information from the Internet, a secondary source rather than information acquired directly from the brand-name drug producers. As a result, the database might be incomplete and inaccurate; it cannot be used as a legal reference concerning the patent status of a drug. The database must therefore be used with caution.

The third database is the drug patent database provided by the Drug Control Division of the Thai FDA.[24] The FDA simply asks new drug applicants to provide patent information on their drugs such as the first country where each patent was granted, application date, date when patent was granted and expiration date. In addition to the information provided, the applicants have to submit an official document relating to the

patent approval and certify the validity of the information provided. However, the penalty for providing invalid patent information is not well elucidated and is likely to be very light or perhaps not exist at all. In spite of the certification of the patent, FDA has no interest in using its resources to recheck the validity of the information provided. New drug applicants would not have any incentive whatsoever to provide all the relevant patents. Completing the list of questions indeed is not without cost such as time. Given the negative net benefit of completing the list, applicants would likely expend minimum efforts in filling out the list. In addition, knowing that it is unlikely that the validity of patent information will be rechecked due to the Department's lack of resources, new drug applicants might provide false information in order to prolong the expiration of a patent. Therefore, it is not rational to believe that the patent information provided is complete and reliable.

While reliable and credible patent information, such as contained in DIP's database, it is not in a user-friendly form, and the two user-friendly databases provided by the FDA are likely to be incomplete and unreliable. Updating and maintaining the database constructed by experts might be difficult and costly in the long run. In addition, the fundamental problem of obtaining all the available data is difficult to solve. Thus, a feasible solution seems to be to improve the database provided by the Department of Drug Control, FDA. A possible way to attack the problem of incompleteness and unreliability is to provide enough incentives to new drug applicants to reveal all relevant patent information. The interaction between NDA and ANDA, under the Hatch-Waxman Act, is a good example of how to make a brand-name drug producer reveal all relevant patent information.

The United States NDA and ANDA

The Hatch-Waxman Act is claimed to create a balance between the innovation of, and access to, drugs. On one hand, it lengthens the brand-name producers' exclusive monopoly rights by giving exclusive rights to compensate the period of difficult and costly clinical trails. On the other, it allows the generic drug producers to submit only a bioequivalence study instead of having to replicate costly clinical trial studies. It provides a shortcut for bringing generic drugs to the market through the process called ANDA, which allows the generic drug to start the approval process before the expiration of patents. In addition, NDA links a patent to drug marketing approval and thus clarifies the ambiguity about the status of the patent. Before we proceed to the Thai proposal, it is important to understand how NDA and ANDA work, as briefly explained below.

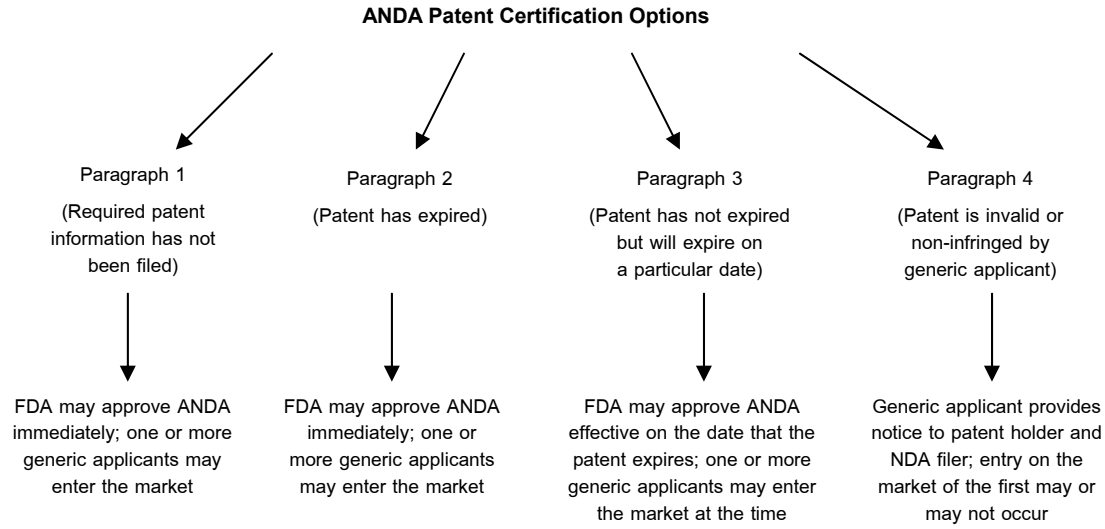
First, a company producing brand-name drugs seeking marketing approval for a new drug has to file a new NDA. In filing the NDA, the applicant must provide the FDA with information regarding relevant patents of the drug subject to NDA. Once the NDA is approved, the patents are listed in a publication, commonly known as the "Orange Book." The main purpose of the Orange Book is to provide information on patents upon which the ANDA application might infringe.[25] It should be noted that more patents can be added later on.[26] Second, a generic drug producer seeking marketing approval on its generic drug has to file an ANDA. In filing the ANDA application, the generic drug company may certify that (a) the required patent information has not been previously filed (referred to as Paragraph 1); (b) the patent has expired (referred to as Paragraph 2); (c) the patent has not yet expired and the applicant will seek approval after patent expiration (referred to as Paragraph 3); or (d) the patent is invalid, or the drug for which approval is being sought will not infringe on the patent (referred to as Paragraph 3). If the brand-name drug adds another patent to the list after the certification, the ANDA applicant must re-certify the newly listed patent.

The marketing approval process depends on the types of certification, as shown in Figure 2. Only the applicant making Paragraph 1 or 2 certification may get FDA approval if its drug meets the other requirements. The applicant making Paragraph 3 certification may get effective FDA approval after the patent expiration date. The applicant making Paragraph 4 certification must give notice to both the patent holder and the NDA applicant. According to the Hatch-Waxman Act 1984, once the patent holder and the NDA applicant get notice, they can choose to file a patent infringement lawsuit within 45 days in order to get an automatic 30-month stay of FDA approval, starting from the date of receiving the notice. The stay will expire at the earliest of (a) the date of the patent expiration, (b) a final court's decision, or (c) the expiration of the stay. If they choose not to file the lawsuit, the FDA approval process may proceed. In addition, the Hatch-Waxman Act also grants an exclusive 180-day marketing approval to the first Paragraph 4 ANDA filer. Figure 3 shows how the 30-month stay and the exclusive 180-day marketing approval affect the marketing approval of new generic drugs.

In contrast to Thailand's current system, the brand-name producers have an incentive to list all relevant patents (or even irrelevant patents) because those patents could trigger an automatic 30-month stay. Since the ambiguity of the patent status is a crucial barrier to the entry of a new generic drug, processes similar to NDA and ANDA would be beneficial to Thai generic producers.

Although NDA and ANDA provide an advantage over the current system used in Thailand, they reportedly have two important loopholes.[27] First, the brand-name producers often list as many patents as possible, both

Figure 2 FDA Approval Process for ANDA



Source: FTC (2002).

relevant and irrelevant to the product, in order to abuse the 30-month stay. Moreover, there is a possibility of multiple 30-month stays caused by newly listed patents. Second, the 180-day exclusivity granted to the first Paragraph 4 ANDA filer opens an opportunity for an anti-competitive agreement between the first filer and the brand-name drug company to delay the entry of the generic drug. This is simply because no other generic producers could enter the market until the 180-day exclusivity period has expired. The exploitation of the loopholes is closely watched by the U.S. Federal Trade Commission (FTC) as a possible anti-competitive practice, which generates numerous losses for consumers and the U.S. government.[28] Learning from the United States experience, Thailand's new drug approval process must close the loopholes in order to truly facilitate the entry of new generic drugs.

V. PROPOSAL FOR FACILITATING THE ENTRY OF NEW GENERIC DRUGS IN THAILAND

To facilitate the entry of new generic drugs, we propose changes in the Thai Patent Act 1999 and the Thai FDA's current marketing approval processes for new drugs and new generic drugs, as follows:

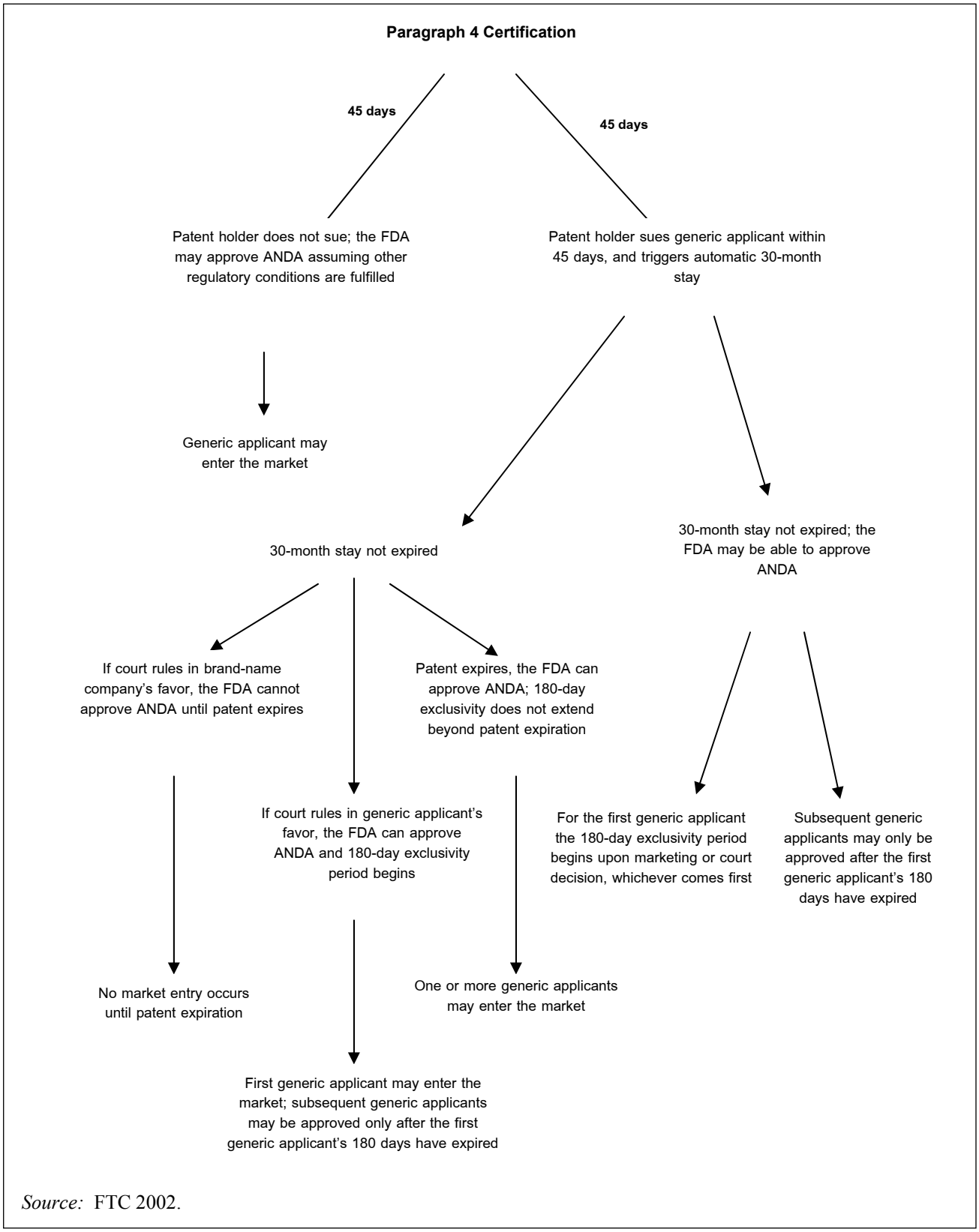
1) The Proposed Amendment of the Thai Patent Act 1999

With regard to amending of the Thai Patent Act 1999, we propose adding a separate clause about the patentability of pharmaceutical products to section 9 of the Thai Patent Act 1999 (the section covers what is not protected by the Patent Law) in a way similar to the Indian Patents (Amendment) Act 2005. The Amended Indian Patents Act, section 3, clause d, explicitly states the conditions under which a pharmaceutical product is not patentable, as follows: "The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant." As explained by the Ministry of Law and Justice of India, clause d means the following: "For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy." With a more stringent patent act for Thailand, it would not be very difficult to search for relevant patents, because there are not many trivial and unobvious secondary patents left. In addition, the risk of patent infringement would be reduced.

2) The Proposed Method for New Drug Marketing Approval in Thailand

Although there would be less relevant patents of the brand-name drug, the risk of patent infringement could still exist, particularly for generic producers lacking expertise in searching patents. As mentioned previously, the current linkage between patents and the

Figure 3 Impacts of the 30-Month Stay and the Exclusive 180-Day Marketing Approval



Source: FTC 2002.

drug marketing approval process does not really solve the problem of ambiguity of patent status because the brand-name drug companies do not really have an incentive to provide the list of all relevant patents to the Thai FDA. In addition, patents granted after marketing approval would not be listed. After the drug is approved,

the list is no longer exclusive because there might be a newly granted patent that has been left out of the list. Consequently, the ambiguity of the patent status would be temporarily solved. Therefore, we propose TNDA and TANDA, similar to those of the United States NDA and ANDA respectively. The proposed processes would provide an incentive to challenge the validity of the patent and to market the generic drug as quickly as possible. Together with the proposed amendment of the Thai Patent Act, the proposed processes would clear up ambiguity about the patents' status.

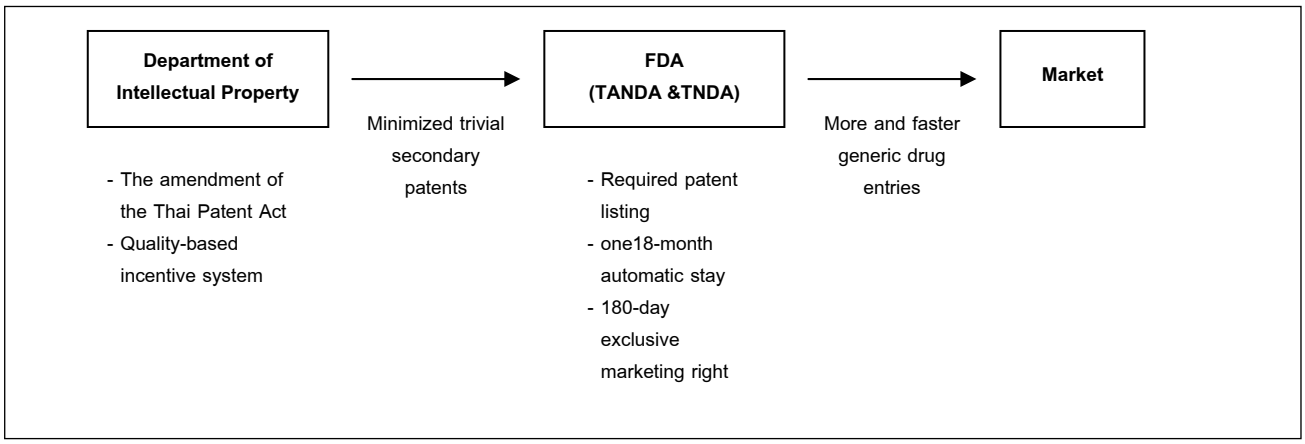
In general, details of TNDA and TANDA are similar to those of the United States NDA and ANDA, except for three factors. First, there would be an 18-month automatic stay instead of a 30-month automatic stay. The rational for the stay is to give both parties and the court enough time to settle infringement litigation. In Thailand, as far as we are concerned, there have only been two cases of patent litigation related to modern pharmaceutical products, the cases of the Government Pharmaceutical Company versus Bristrol-Myers Squibb. The first litigation, mainly involving invalidity of claims, lasted about 17 months. The second litigation, involving validity of a patent, lasted about 15 months. Thus, an 18-month stay would be appropriate and give enough incentive for the brand-name drug companies to list all relevant patents. In fact, the incentive is overwhelming, since an 18-month stay is roughly twice as long as the average time used in the current NDA process for imported drugs, i.e., 9.3 months.[29] Second, only one 30-month automatic stay should be granted. With the enactment of an amended Thai Patent Act, the listing of trivial secondary patents is unlikely and thus multiple 30-month stays would perhaps be rare anyway. Third, to prevent anti-competitive agreements between the brand-name drug and the first ANDA filer, 180-day exclusive marketing rights shall be granted to the first generic company that markets a drug under Paragraph 4 certification. In addition, the 180-day exclusive marketing rights would increase competition among generic producers to bring new generic drugs to the market as quickly as possible.

The proposed new drug marketing approval processes would work congruently with the proposed amendment of the Thai Patent Act to help facilitate the entry of new generic drugs in Thailand, as shown in Figure 4. Every proposed feature is designed to complement one another and work as a system, as one feature alone would never succeed. More importantly, they are necessary but not sufficient conditions to facilitate the entry of new generic drugs. Without strict enforcement of the law and a sufficient amount of good-quality patent examiners, the problem would not be easily solved. Therefore, it is important for the government to provide adequate funds and resources to improve the quality of patent examiners. Moreover, an appropriate reward and punishment scheme could be used to give an incentive for patent examiners to enforce the Patent Law strictly. One possible scheme is that the patent examiners could be paid monthly bonuses that would depend on the quality of examined patents. The patent examiner would get one point for each granted patent, but would get minus 10 points for each patent that generic drug companies sue and eventually resulting in the withdrawal of the patent.[30] The amount of the bonus would be 200 baht times the net number of points per month.[31]

VI. CONCLUSION

The ambiguity of patent status is certainly one of the important barriers to entry for producers of Thai generics. In this article, focusing on the problem of ambiguity of patent status, we propose an amendment to the Thai Patent Act 1999: a quality-based incentive system for patent examiners and TNDA and TANDA to facilitate the timely entry of generic drugs. All proposed features would work as a system as one feature alone would not be fully effective. The proposed system would lead to more and faster new generic entries. The amendment of the Thai Patent Act together with the quality-based incentive system would reduce the number of trivial secondary patents granted by DIP. As a result,

Figure 4 Proposed Process for Facilitating Entry of New Generic Drugs in Thailand



the risk of patent infringement would be reduced. TNDA and TANDA would solve the ambiguity about patent status and further reduce the risk of patent infringement. In addition, the 180-day exclusive marketing rights would not only provide an incentive for the generic producer to challenge the validity of patents that block entry, but also increase competition between the generic producers to bring new generic drugs to the market as soon as possible. However, the proposed system is a necessary but not sufficient condition to bring new generic drugs to market successfully. There are other important barriers to entry, such as the ability of the generic producers, the sufficiency of bioequivalence facilities, and monopolies in generic markets.

ENDNOTES

[1] Drug consumption is calculated from the following formula: consumption value = production value – (export value – import value). All data have been acquired from the Thai Drug Control Division, Food and Drug Administration, Ministry of Public Health.

[2] Instead of going through extremely expensive clinical trials, generic drug producers may demonstrate that a generic drug is the bioequivalent of a brand-name drug and receive marketing approval from the Food and Drug Administration (FDA). Bioequivalence means that the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the brand-name drug. The cost of conducting a bioequivalence study trail could be as high as 1-2 million baht which is considered high for the Thai producers, particularly for a study targeting a new off-patent drug. As a result, it is less likely for some generic producers, particularly small and medium-sized producers, to enter the market.

[3] DiMasi, Hansen, and Garbowski (2002) estimate drug development costs to be US$ 802 million.

[4] Angell (2005) found that only 14 percent of 415 newly approved drugs in the period 1998-2002 could be called innovative drugs, that is, they contained new molecules and were characterized by significant improvements compared with marketed drugs.

[5] For instance, Crestor, Lipitor, Zocor, Pravachol, Lescol are drugs used to lower cholesterol, and they are variations of Mevacor.

[6] These important drugs include Taxol, Epogen, and Gleevec.

[7] OTC drugs are drugs that are available to consumers without a prescription. In the United States, according to the Hatch-Waxman Act, a drug company can get three years of exclusivity by switching its drug from prescription to OTC if it can show that consumers can understand how to use the drug properly.

[8] Although the scope of life-cycle management strategies is broader than the scope of the evergreening patent, in the literature the evergreening patent and life-cycle management approaches are sometimes used interchangeably.

[9] An evergreening patent also includes a practice called double patenting. Double patenting is a practice in which a patent claims the same uniqueness as an earlier issued patent.

[10] For example**,** a brand-name drug producer might allege that a generic drug company is infringing on a new use patent. Only doctors who prescribe a generic drug for patients—if it has a new use—can directly infringe on the new use patent. Being aware of the risk of patent infringement, doctors might avoid the risk of patent infringement by sticking with a brand-name drug. However, in fact, a patentee usually sues generic producers for inducing patent infringement because they sold the drugs to the doctors.

[11] For example, salts**,** polymorphs, metabolites, pure form, isomers and mixture of isomers.

[12] More details are available in Angell (2005) and FTC (2002).

[13] Prilosec is marketed in Thailand under the name of Losec. Losec is scheduled to go off patents in November 2018.

[14] More details are available in Angell (2005) and FTC (2002).

[15] Intercontinental Marketing Services (IMS).

[16] A polymorph is a specific crystalline form of a compound that can crystallize in different forms.

[17] Application number 062645.

[18] Zoloft is used to treat depression and anxiety.

[19] Taxol is used to treat some types of cancer.

[20] Augmentin is used to treat many different bacterial infections, such as sinusitis, pneumonia, ear infections, bronchitis, urinary tract infection, and infections of the skin.

[21] The database is accessible from the following URL: <http://www.ipic.moc.go.th/>.

[22] Rare exceptions include the titles of inventions that sometimes were given in English when the applicants submitted their applications.

[23] The database is accessible from the following URL: <http://www.fda.moph.go.th/>.

[24] The database is accessible from the following URL: <http://wwwapp1.fda.moph.go.th/drug/zone_service/ser019.asp>.

[25] Given advanced technology in patent-searching techniques and in monitoring relevant new patents, some brand-name companies actually rely on information in the Orange Book.

[26] There are certain rules that govern listing in the Orange Book. However, those rules are not strictly enforced due to the lack of FDA resources. For practical purposes, the brand-name drug can list as many patents (both relevant and irrelevant to the products) as they like at any time, even if the drug is already on the market.

[27] FTC (2002) and Angell (2005) provide an excellent review of the issue.

[28] In fact, FTC (2002) suggested recommendations regarding the loopholes; however, the U.S. House of Representatives did not approve those recommendations.

[29] Chutima et al. (2005).

[30] This is a proposed number. It could be substituted by any appropriate number.

[31] This is a proposed amount. It could be substituted by any appropriate figure.

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