

**Jean Kelly**

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**From:** Nancy Adams [NAdams@phrma.org]  
**Sent:** Monday, December 06, 2010 12:54 PM  
**To:** Jean Kelly  
**Subject:** RE: Thailand: renewal of CLs for two drugs: request for details

Thanks. Let us know if we can help further. N

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**From:** Jean Kelly [mailto:Jean.Kelly@trade.gov]  
**Sent:** Monday, December 06, 2010 12:39 PM  
**To:** Nancy Adams  
**Subject:** RE: Thailand: renewal of CLs for two drugs: request for details

Nancy-

I appreciate this information. I also learned much from your detailed presentation last Wednesday.

Thanks again.

Jean

Jean Kelly  
Thailand/Philippines/Burma desk officer  
Office of the Pacific Basin  
International Trade Administration  
U.S. Department of Commerce  
tel: 202-482-3448  
fax: 202-482-3316  
[Jean.Kelly@trade.gov](mailto:Jean.Kelly@trade.gov)

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**From:** Nancy Adams [mailto:NAdams@phrma.org]  
**Sent:** Monday, December 06, 2010 12:34 PM  
**To:** Anthony Cino; Jean Kelly  
**Subject:** RE: Thailand: renewal of CLs for two drugs: request for details

Jean,

The drugs are both HIV/AIDS drugs: Stocrin (Merck/MSD) and Kaletra (Abbott). The original announced CL was 11/29/06 on Stocrin and 1/24/07 for Kaletra. Neither were due to expire for several years (I think five years from date of announcement).

Nancy

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**From:** Anthony Cino  
**Sent:** Monday, December 06, 2010 10:27 AM  
**To:** Jean Kelly  
**Cc:** Nancy Adams  
**Subject:** RE: Thailand: renewal of CLs for two drugs: request for details

Jean,

I'm out on vacation until Wednesday, so I am suggesting you go straight to the source on this. Nancy is cc'ed here and may be able to fill you in. If you can't connect before Wednesday, I would be happy to help get any relevant information to you.

All the best,  
Tony

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**From:** Jean Kelly [<mailto:Jean.Kelly@trade.gov>]  
**Sent:** Mon 12/6/2010 10:12 AM  
**To:** Anthony Cino  
**Subject:** Thailand: renewal of CLs for two drugs: request for details

Tony-

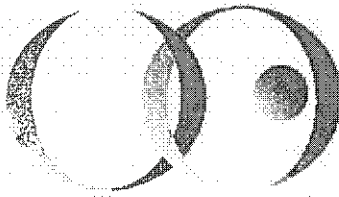
Following up on my voicemail this morning, I would appreciate your help in regard to any details that you may be able to provide regarding actions by the Thai Government to renew the CLs on two drugs.

Nancy Adams mentioned this issue at a Thai IPR roundtable last week, but I would like you to confirm the names of the drugs and the companies involved and the status of the CL renewals.

Thanks very much.

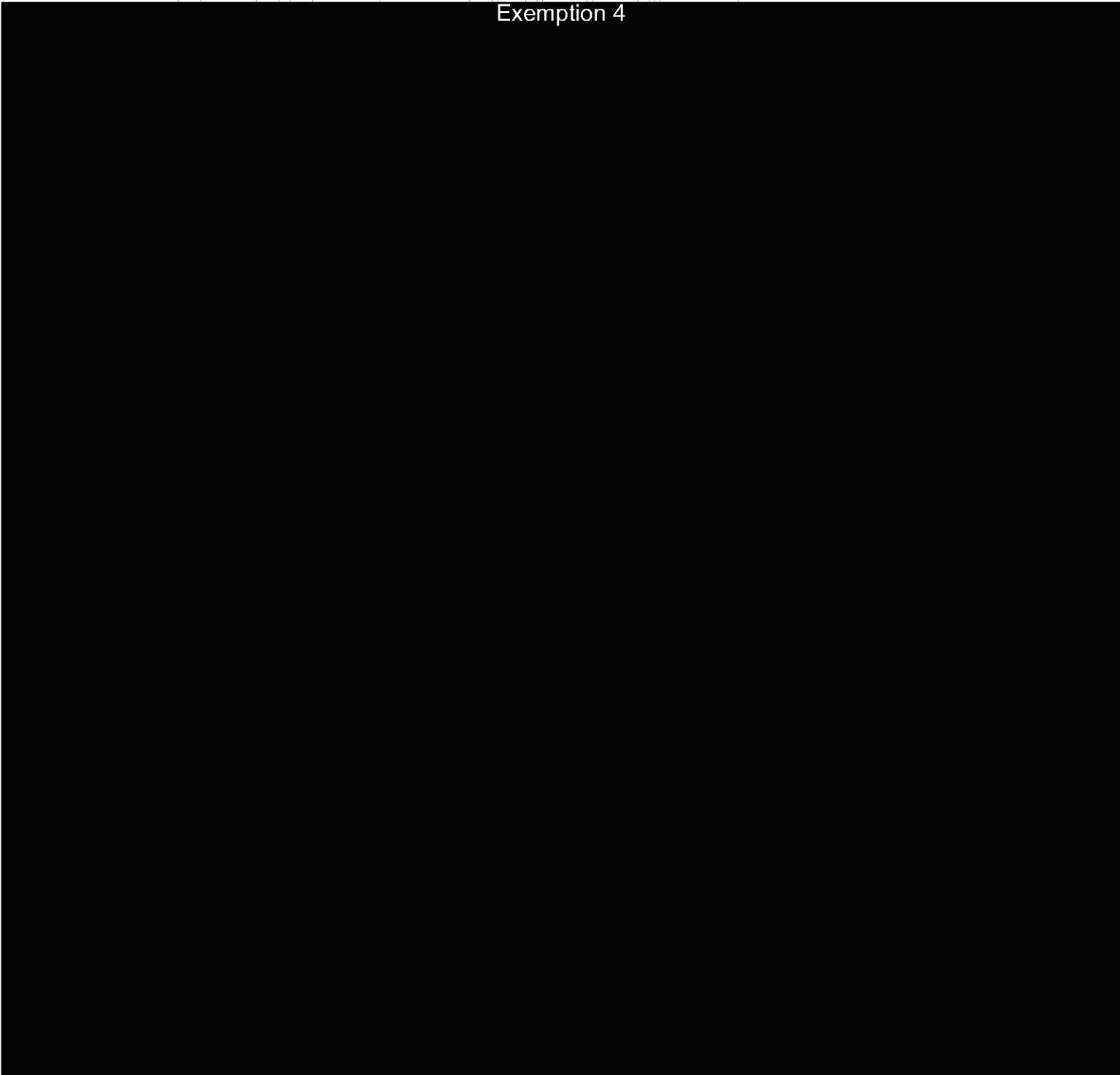
Jean

Jean Kelly  
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**U S - A S E A N**  
BUSINESS COUNCIL, INC.

Exemption 4







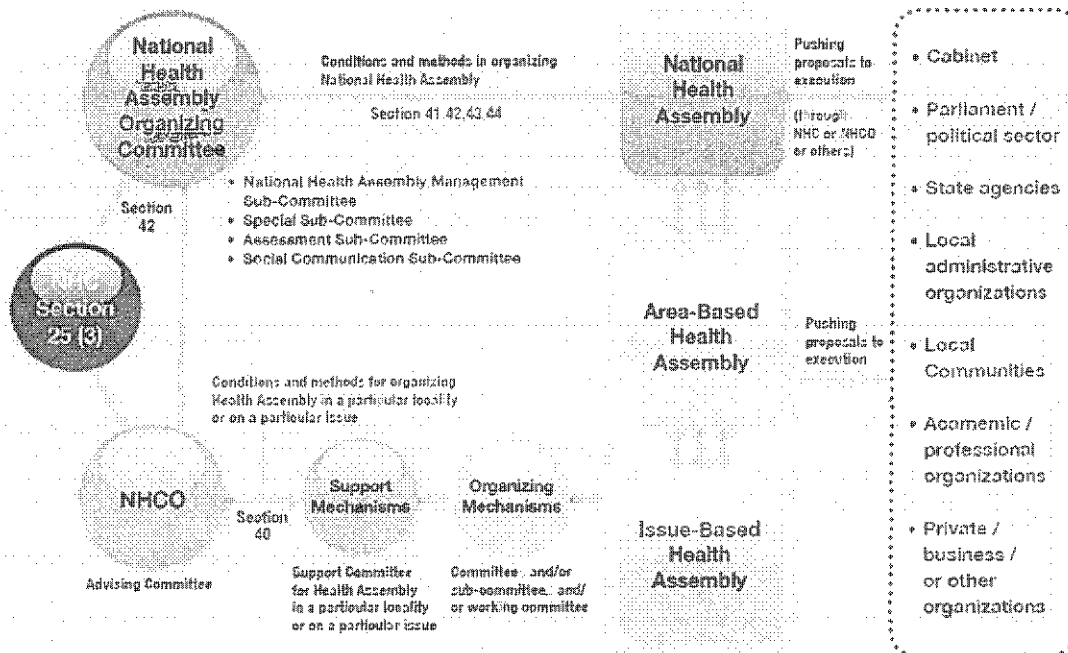


## National Health Assembly – Thailand

Prior to the enactment of the National Health Act (2007), National Health Assemblies were held in Thailand as a function of the Prime Minister's Office Health System Reform. There were 6 such annual Assemblies held from 2001 to 2006, and these Assemblies focused on passing a National Health Act, which passed in 2007. The National Health Act mandated the creation of the National Health Commission (chaired by the Prime Minister), the National Health Commission Office (under the supervision of the Prime Minister), and the organization of the National Health Assembly. The first National Health Assembly under the National Health Act was held in December 2008.

The National Health Assembly is intended to provide a platform that links political, academia, and the people in the policy making decisions. The process, put into place through the National Health Act, also provides a direct channel for resolutions and strategies to be approved by the Prime Minister and the Cabinet.

### Health Assembly Systems and Mechanisms



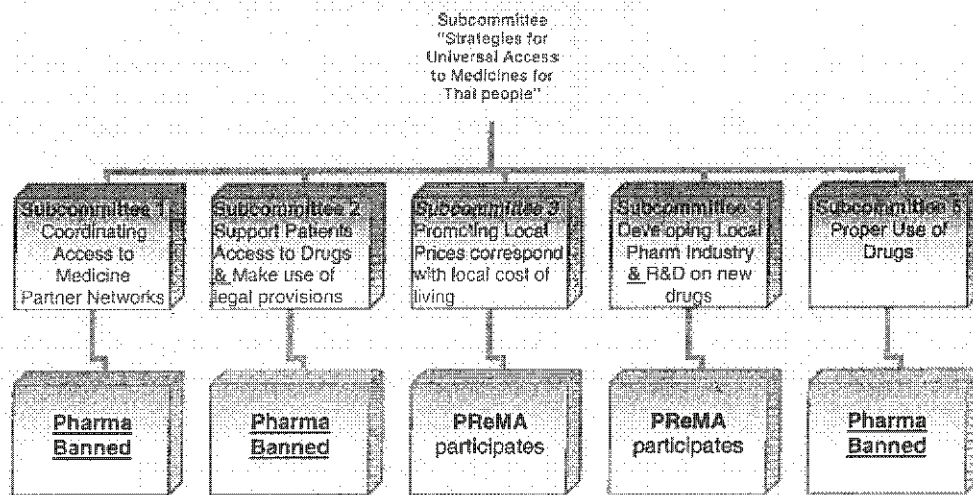
### Outcomes of 2008 National Health Assembly

In December 2008, the National Health Assembly 2008 generated 12 resolutions. One of the resolutions from NHA 2008 is "*Adopt Strategies for Universal Access to Medicine for Thai People*". All 12 resolutions were adopted by the National Health Commission and approved by the Cabinet.

Each approved Resolution is accompanied strategies for implementation. For the Resolution to "*Adopt Strategies for Universal Access to Medicine for Thai People*", the following 7 strategies were proposed and approved by the Cabinet. The next step for the National Assembly was to form 5 subcommittees to develop further recommendations and objectives for each of the strategies.

#### 7 Strategies to "Universal Access to Medicine" (5 Subcommittees formed):

- 1) Coordinating partner networks for access to drugs
- 2) Supporting patients to get access to drugs and participate in health care promotion
- 3) Promoting local drug prices that correspond with the local cost of living
- 4) Developing the local pharmaceutical industry
- 5) Making use of legal provisions and/or reducing barriers deriving thereof
- 6) Proper (Rational) use of drugs
- 7) Research and development of new drugs.



After establishing these five subcommittees, "objectives" for each the subcommittees were discussed and agreed upon by NHA leadership. The deliberation of the "objectives" occurred without any public input. It is in these objectives under Subcommittee 3, where "implementing TRIPS flexibilities on 10 traded items" has been mentioned. Although no government agency has taken credit for these statements, and they are most likely a product of NGO/MoPH bureaucrat closed door discussion, the "objectives" indicate that the desired outcomes for the subcommittees have already been agreed upon by the core participants and industry's input will not be heard in this forum.

| Subcommittee   | Chairperson                                  | Objective(s)   |
|--|--|--|
| <b>Subcommittee No. 3</b><br>Promoting local drug prices to correspond with the local cost of living | <b>Chairman:</b><br>Dr. Siriwat Thiptraradol | <b>Gov't Objectives:</b> <ul style="list-style-type: none"> <li>Decrease median prices of patented products or monopolized products to the same level as in other developing countries or countries with similar economic status</li> <li>Implement TRIPS flexibilities on at least 10 traded items</li> </ul> |

| Subcommittee  | Chairperson                               | Objective(s)  |
|---|---|---|
| <b>Subcommittee No. 4</b><br>Developing the local pharmaceutical industry, &<br>Research and development of new drugs | <b>Chairman:</b><br>FDA Secretary General | <b>Gov't Objectives:</b> <ul style="list-style-type: none"> <li>Reduce access problems by increasing the capacity of local manufacturers to produce at least 20 new products within a period of 5 years</li> <li>Produce a minimum of 20 safe and effective herbal medicines with high quality within a period of 5 yrs.</li> </ul> |

PReMA has been barred from participating on 3 of the Access Strategy subcommittees because of industry's conflict of interest. This exclusion has been raised with Deputy Minister Alongkorn on September 2. The Thailand Trade Representative and the Prime Minister have also been made aware of the lack of transparency in the NHA process and working groups. The Deputy Minister of Commerce was initially not aware of the NHA subcommittees, but after being informed stated that all stakeholders should participate, and that he would raise this issue with Ministry of Public Health and the Prime Minister.

Industry has also raised the lack of transparency with the Ministry of Public Health, who noted that having companies participate would be difficult.



The 3 Subcommittees (out of 5) which PReMA has no participation.

| Subcommittee   | Chairperson                                    | Objective(s)  |
|--|--|---|
| <b>Subcommittee No. 1</b><br>Coordinating access to medicine partner networks  | <b>Chairman</b><br>Dr. Siriwat Thiptraradol    | Partner networks have participatory action plans to develop the systems and processes to improve access   |
| <b>Subcommittee No. 3</b><br>Supporting patients to get access to drugs and participate in health care and health promotion<br>& Making use of legal provisions and/or reducing barriers to ensure that there is no barrier to access to drugs | <b>Chariman</b><br>Dr. Jirapom Limpananond     | Increase patients participation in the health care and health promotion by a minimum of 5% per year<br><br>At least 80% of patients have medicine |
| <b>Subcommittee No. 5</b><br>Proper use of drugs   | <b>Chariman</b><br>Dr. Pongpisuth Chongudomsuk | Reduce irrational use of targeted medicines by a minimum of 50% within 5 years  |

There are other resolutions from the NHA 2008 that are of concern such as Resolution: "Participation of the People's Sector in Free Trade Agreement Policies". We have yet to see any strategies from this Resolution, and there are yet no subcommittees formed. However, there has been one meeting for "input" whose participants included AIDS Access, FTA Watch. PReMA was not allowed to attend this August 2009 meeting and therefore has not been able to provide any input.

Appointment for NHA subcommittees no. 1/2552

August 26, 2009

(Unofficial Translation)

**1. Subcommittee 1: Coordinating access to medicine partner networks subcommittee**

|      |   |                           |
|------|---|---------------------------|
| 1.1  | Mr. Siriwat Tiptaradol                      | President                 |
| 1.2  | Secretariat of Food and Drug Administration | Committee                 |
| 1.3  | Ms. Kannikar Kijivechagul                   | Committee                 |
| 1.4  | Asso. Prof. Jiraporn Limpananon             | Committee                 |
| 1.5  | Mr. Parinya Poathong                        | Committee                 |
| 1.6  | Mr. Pongpisoot Jongudomsuk                  | Committee                 |
| 1.7  | Prof. Assistant Yupadee Sirisinsakul        | Committee                 |
| 1.8  | Mr. Winit Ussavakijwiree                    | Committee                 |
| 1.9  | Asso. Prof. Witthaya Kulsomboon             | Committee                 |
| 1.10 | Ms. Sukanya Jiarapong                       | Committee                 |
| 1.11 | Ms. Unchalee Jitraknatee                    | Committee                 |
| 1.12 | Prof. Assistant Wanna Sreewiriyanyuparb     | Committee and Secretary   |
| 1.13 | Ms. Worasuda Yoongthong                     | Committee and Secretary   |
| 1.14 | Ms. Tipicha Posayanon                       | Committee asst. Secretary |
| 1.15 | Ms. Sareeraroj Sukamolsan                   | Committee asst. Secretary |

**Objectives of Subcommittee 1**

- To co-ordinate, collect and synthesize Strategy for Thai access to medicine draft and develop related system and mechanism.
- Form a working level taskforce to process related plans
- Other tasks that the Committee (.....) assign.

**2. Subcommittee 2: Supporting patients to get access to drugs and participate in health care and health promotion and Making use of legal provisions and/or reducing barriers deriving thereof to ensure that there is no barrier to access to drugs subcommittee**

|      |  |                         |
|------|--|-------------------------|
| 2.1  | Assoc. Prof. Jiraporn Limpananon                               | President               |
| 2.2  | Secretariat of Food and Drug Administration or representative  | Committee               |
| 2.3  | President of The Medical Council of Thailand or representative | Committee               |
| 2.4  | President of The Pharmacy Council or representative            | Committee               |
| 2.5  | Representative from Department of Intellectual Property, MOC   | Committee               |
| 2.6  | Representative from Thai Network for People Living HIV/AIDs    | Committee               |
| 2.7  | Representative from Network for Kidney patients                | Committee               |
| 2.8  | Representative from Aids Access                                | Committee               |
| 2.9  | Representative from National Health Security Office            | Committee               |
| 2.10 | Director of International Health Policy Program Thailand       | Committee               |
| 2.11 | Prof. Pichaisak Horayangkul                                    | Committee               |
| 2.12 | Asso. Prof. Witthaya Kulsomboon                                | Committee               |
| 2.13 | Prof. Assistant Wanna Sreewiriyanyuparb                        | Committee and Secretary |
| 2.14 | Ms. Kannikar Kijivechagul<br>assistant                         | Committee and Secretary |
| 2.15 | Ms. Sareeraroj Sukamolsan<br>assistant                         | Committee and Secretary |

**Objective**

- Study the situation for drafting strategy for supporting patients access to medicine and help supporting health and/or decrease Law obstacles for not blocking patients access to medicine which correspond with solution from Health Samatcha No.1 2008

- Drafting action plan for patient access to medicines on strategy 2 and 5 and then propose to the Committee (.....)
- Form a working level taskforce to process related plans.
- Other tasks that the Committee (.....) assign.

### 3. Subcommittee 3: Promoting local drug prices that correspond with the local cost of living

|      |  |                         |
|------|--|-------------------------|
| 3.1  | Dr. Siriwat Tiptaradol                                       | President               |
| 3.2  | Director of Pharmaceuticals Industry Club or representative  | Committee               |
| 3.3  | Director of Herbal Product Association or representative     | Committee               |
| 3.4  | Director of PReMA or representative                          | Committee               |
| 3.5  | Representative from Department of Internal Trade, MOC        | Committee               |
| 3.6  | Representative from Department of Intellectual Property, MOC | Committee               |
| 3.7  | Representative from Health Service Support, MoPH             | Committee               |
| 3.8  | Director from Thai Drug Control Division or representative   | Committee               |
| 3.9  | Ms. Kannikar Kijtivechagul                                   | Committee               |
| 3.10 | Asso. Prof. Jiraporn Limpananon                              | Committee               |
| 3.11 | Asso. Prof. Cha-ornsin Suksreewong                           | Committee               |
| 3.12 | Prof. Assistant Niyada Kiatyingangsulee                      | Committee               |
| 3.13 | Asso. Prof. Witthaya Kulsomboon                              | Committee               |
| 3.14 | Mrs. Wandee Pokakul  | Committee               |
| 3.15 | Ms. Saree Ongsomwang   | Committee               |
| 3.16 | Prof. Assistant Wanna Sreewiriyannuparb                      | Committee and Secretary |
| 3.17 | Ms. Anchalee Jitraknatee                                     | Committee and Secretary |
| 3.18 | Ms. Jitrawee Jitarachoti<br>assistant                        | Committee and Secretary |

#### Objective

- Study situation for drafting strategy for promoting local drug prices that correspond with the local cost of living which correspond with solution from Health Samatcha No.1 2008
- Drafting action plan for patient access to medicines on strategy 3 and then propose to the Committee (.....)
- Form a working level taskforce to process related plans.
- Other tasks that the Committee (.....) assign.

### 4. Subcommittee 4: Developing the local pharmaceutical industry

|      |  |                         |
|------|--|-------------------------|
| 4.1  | Representative from Thai Red Cross Society                                     | President               |
| 4.2  | Secretariat of Food and Drug Administration                                    | Committee               |
| 4.3  | Director of Herbal Product Association or representative                       | Committee               |
| 4.4  | Director of PReMA or representative  | Committee               |
| 4.5  | Representative from Ministry of Industry                                       | Committee               |
| 4.6  | Representative Department of Thai Traditional and Alternative Medicine, MoPH   | Committee               |
| 4.7  | Representative from Department of Business Development                         | Committee               |
| 4.8  | Representative from National Science and Technology Capability                 | Committee               |
| 4.9  | Representative from Bureau of Policy and Strategy, MoPH                        | Committee               |
| 4.10 | Representative from Bureau of Drug and Narcotic, Department of Medical Science | Committee               |
| 4.11 | Director of Thai Drug Control Division   | Committee               |
| 4.12 | Director of Herb Research Institute, Department of Medical Science             | Committee               |
| 4.13 | Mr. Chernporn Tengumnouy   | Committee               |
| 4.14 | Mr. Suchart Jongprasert  | Committee               |
| 4.15 | Ms. Supaporn Pitiporn  | Committee               |
| 4.16 | Mrs. Ajchara Aeksangpong   | Committee               |
| 4.17 | Ms. Sukanya Jiarapong  | Committee and Secretary |
| 4.18 | Mr. Parinya Poathong   | Committee and Secretary |
| 4.19 | Ms. Achiraya Lertprotsombat<br>assistant                                       | Committee and Secretary |

**Objective**

- Study situation for drafting strategy for develop local pharmaceutical industry and strategy for research and develop new medicines correspond with solution from Health Samatcha No.1 2008.
- Drafting action plan for patient access to medicines on strategy 4 and 7 and then propose to the Committee (.....)
- Form a working level taskforce to process related plans.
- Other tasks that the Committee (.....) assign

**5. Subcommittee No. 5 Proper use of Drugs**

|      |   |                         |
|------|---|-------------------------|
| 5.1  | Pongpisut Jongudomsuk   | President               |
| 5.2  | Director of Community Pharmacy Association(Thailand) or representative        | Committee               |
| 5.3  | Director of The Association of Hospital Pharmacy (Thailand) or representative | Committee               |
| 5.4  | Representative from The Comptroller General's Department, Ministry of Finance | Committee               |
| 5.5  | Representative from Consortium of Thai Medical Schools                        | Committee               |
| 5.6  | Representative from The Medical Council of Thailand                           | Committee               |
| 5.7  | Representative from Pharmacy for Society foundation                           | Committee               |
| 5.8  | Representative from Public Health and Development foundation                  | Committee               |
| 5.9  | Representative from Center of Pharmacy Education (Thailand)                   | Committee               |
| 5.10 | Representative from The Pharmacy Council                                      | Committee               |
| 5.11 | Representative from National Health Security Office                           | Committee               |
| 5.12 | Director of Thai Drug Control Division  | Committee               |
| 5.13 | Director of The Institute of Hospital Quality Improvement & Accreditation     | Committee               |
| 5.14 | Prof. Assistant Niyada Kiatyingangsulee                                       | Committee               |
| 5.15 | Ms. Pompit Silkawoot  | Committee               |
| 5.16 | Mr. Pison Jongtrakul  | Committee               |
| 5.17 | Mr. Witthaya Sreemada   | Committee               |
| 5.18 | Asso. Prof. Sayomporn Sirinavin   | Committee               |
| 5.19 | Ms. Saree Ongsomwang  | Committee               |
| 5.20 | Ms. Worasuda Yoongthong   | Committee and Secretary |
| 5.21 | Prof. Assistant Yupadee Sirisinsuk  | Committee and Secretary |
| 5.22 | Ms. Wannisa Tientawee<br>assistant  | Committee and Secretary |

**Objective**

- Study situation for drafting strategy for develop Proper use of drugs correspond with solution from Health Samatcha No.1 2008.
- Drafting action plan for patient access to medicines on strategy 6 and then propose to the Committee (.....)
- Form a working level taskforce to process related plans.
- Other tasks that the Committee (.....) assign

## List of Participants for National Health Assembly December 2009

### Social-Private (34)

Agriculture and Food network  
Disabled network  
Consumer protection on service and health products network  
General consumer protection network  
Volunteer Spirit network  
Volunteer Spirit for assistance network  
Specific network  
Children and Family, Education and Media network  
Youth and Charity network  
Youth and Development network  
Business for Society network  
Legal expert networks  
Elderly networks  
Woman and assistance network  
Woman and knowledge development network  
Politic and administration development network  
Social development networks 1  
Social Development networks 2  
Business sector network  
Local Community Knowledge network  
City network  
Labour network  
Christianity network  
Buddhism network  
Islam Network  
Sufficiency economy network  
Community council network  
Health support on specific issue network  
Health support network  
Environment for development network  
Environment for protection/ restore  
Media network  
Health Volunteer network  
Private sectors on Health issue network

### Academics-Professionals (24)

Profession Commission according to the practice of the art of healing Act network  
Profession of Physical Therapy network  
Profession of Health network  
Profession of Health network (Management)  
Profession of Dentistry network  
Profession of Medical Technology network  
Profession of Nursing network  
Profession of Medicine network  
Profession of Pharmacy network  
Profession of Physical Therapy Education network  
Profession of Social and Environment network  
Profession of Dentistry education network  
Profession of Medical Technology Education network  
Profession of Nursing Education network  
Profession of Medicine Education network  
Profession of Pharmacy Education network  
Professional of Public Health Education  
Academic Institute network 1  
Academic Institute network 2  
Academic Institute network 3  
Academic Institute network 4

Academic Institute network 5  
Academic Institute on Public policy network  
Anamai doctors network

### Government-Political (44)

Public Relations Department  
Ministry of Defense  
Ministry of Finance  
Ministry of Foreign Affair  
Ministry of Social Development -Human Security  
Ministry of Tourism and Sports  
Ministry of Agriculture and Cooperatives  
Ministry of Transport  
Ministry of Natural Resources and Environment  
Ministry of Information Communication Technology  
Ministry of Energy  
Ministry of Commerce  
Ministry of Interior  
Ministry of Justice  
Ministry of Labour  
Ministry of Culture  
Ministry of Science and Technology  
Ministry of Education  
Ministry of Public Health (Medical Development)  
Ministry of Public Health (Public Health Development)  
Ministry of Public Health (Public Health Service Support)  
Ministry of Public Health (Permanent secretary office)  
Ministry of Industry  
Buddhism organization  
Commission of the senate  
Commission of the House of Representatives  
Democrat Party  
Government Party  
King Prajadhipok's Institute/ Political Development Council  
Community Organizations Development Institute  
National Economic and Social Advisory Council  
Provincial Administration Organization Council Thailand  
Tambon Administration Organization Council Thailand  
The National Municipal League of Thailand  
Bureau of the Budget  
Thai Health Promotion Foundation  
Office of the Consumer Protection Board  
Office of the National Economic and Social Development Board  
Office of the National Human Rights Commission of Thailand  
Royal Thai Police  
Administrative Court / Constitutional Court / Justice Court  
National Health Security Office  
The Prime Minister's Office  
Bangkok Metropolitan Authority

### Thailand Provinces (76)

Including representatives from 76 Provinces of Thailand

**Jean Kelly**

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**From:** Andrea Cornwell on behalf of Andrea Cornwell [Andrea.Cornwell@trade.gov]  
**Sent:** Monday, March 15, 2010 3:03 PM  
**To:** Molly Torsen; Jean Kelly; Jeffrey Gren; Jane Earley  
**Subject:** FW: Thai civil society presentation by telephone relating to the Special 301 Public Hearing  
**Attachments:** White Paper CL-EN.pdf; White paper CL II FEB 08-ENG.pdf

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**From:** Karol Pinha, Paula C. [Paula\_KarolPinha@ustr.eop.gov]  
**Sent:** Friday, March 12, 2010 4:19 PM  
**To:** Andrea Cornwell; Bae, Rachel S.; Ferriter, Karin L.  
**Subject:** FW: Thai civil society presentation by telephone relating to the Special 301 Public Hearing

Documents from this morning's call with the Thai NGO. Enjoy!! ☺

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**From:** Jon Ungphakorn [mailto:[ungjon@usa.net](mailto:ungjon@usa.net)]  
**Sent:** Friday, March 12, 2010 2:44 PM  
**To:** Karol Pinha, Paula C.  
**Subject:** Thai civil society presentation by telephone relating to the Special 301 Public Hearing

13th March 2010

Dear Paula,

Thank you very much for your telephone call yesterday which allowed three of us, as representatives of Thai civil society organisations working on access to health, to present our position regarding Thailand's PWL status, as part of the Special 301 Review process.

Apart from myself, the other two participants were Mr. Chalerm Sak Kittittrakul - representative of the Foundation for AIDS Rights (FAR); and Ms. Kannikar Kijtiwatchakul - representative of the Health Consumer Protection Program, Chulalongkorn University.

I have attached for your reference the two Thai Government white papers that were issued in February 2007 and February 2008 explaining the Government's announcements of compulsory licensing of life-saving medicines for non-commercial use. The issues of transparency and prior negotiations are covered in the two documents. It must be reiterated, however, that under TRIPS Article 31 paragraph b, there are no preconditions required for Government non-commercial use of compulsory licensing.

with best regards,

Jon Ungphakorn  
Board Secretary, AIDS Access Foundation

## READOUT: AIDS ACCESS FOUNDATION SPECIAL 301 BRIEFING

March 12, 2010

### Participants

AIDS Access Foundation  
Health Consumer Protection Program  
Foundation for AIDS Rights  
USTR: Rachel Bae, Paula Pinha  
DOC: Andrea Cornwell  
USPTO/USTR: Karin Ferriter

### Summary:

**AIDS Access Foundation:** Compulsory licensing was cited in raising Thailand to PWL in 2007. But we feel that use of CLs should not be justification for raising a country to PWL because Thailand was completely compliant with TRIPs requirements for compulsory licensing: it was non-commercial, and we should not be penalized for complying with an international agreement. If the US believed we did not comply, then the US should have challenged us at the WTO. Thailand has over one million people with HIV/AIDS, a much larger percentage than in the US, but we have just a small portion of what the US has in GDP. Thais do not have access to life-saving ARVs because they cannot afford them – we needed to CL the drugs to save the lives of many thousands of Thais. Because of the CL and increased access to drugs, the death rate from HIV/AIDS has dropped by 80%. But now, we are facing difficulties with regard to expensive second-line drugs. Thais and other developing country citizens should have the same access to life-saving drugs. USTR should instead focus its efforts on persuading the pharmaceutical industry to lower its prices. We hope that under the new Obama Administration there will be a shift on access to medicines policy. Thailand's listing should not be linked in any way to acting within its rights.

**Foundation for AIDS Rights:** We consider USTR's willingness to speak with us and other developing country civil organizations a sign of improvement. Thailand has simply exercised its legal right to increase access to essential medicines in compliance with international treaties. USTR must not only consider economic and IPR concerns, but humanity and health issues, too. USTR should stop pressuring Thailand and other developing countries through 301.

**Health Consumer Protection Program:** We hope that the Obama Administration will take into consideration the needs of Thai patients. If nothing changes, I feel pity for the Americans.

### Q&A:

**USTR:** Please keep in mind that the CL issue was just one of many issues that we considered in raising and keeping Thailand on the PWL.

**AIDS Access Foundation:** Fine, but TRIPs-compliant actions should not even be considered.

**USTR:** The main concern with the CLs was non-transparency in how they were issued.

**AIDS Access Foundation:** We have plenty of documentation on negotiations between US pharmaceutical companies on pricing for the ARVs, but none of these negotiations resulted in

**READOUT: AIDS ACCESS FOUNDATION SPECIAL 301 BRIEFING**  
March 12, 2010

Participants

AIDS Access Foundation  
Health Consumer Protection Program  
Foundation for AIDS Rights  
USTR: Rachel Bae, Paula Pinha  
DOC: Andrea Cornwell  
USPTO/USTR: Karin Ferriter

Summary:

**AIDS Access Foundation:** Compulsory licensing was cited in raising Thailand to PWL in 2007. But we feel that use of CLs should not be justification for raising a country to PWL because Thailand was completely compliant with TRIPs requirements for compulsory licensing: it was non-commercial, and we should not be penalized for complying with an international agreement. If the US believed we did not comply, then the US should have challenged us at the WTO. Thailand has over one million people with HIV/AIDS, a much larger percentage than in the US, but we have just a small portion of what the US has in GDP. Thais do not have access to life-saving ARVs because they cannot afford them – we needed to CL the drugs to save the lives of many thousands of Thais. Because of the CL and increased access to drugs, the death rate from HIV/AIDS has dropped by 80%. But now, we are facing difficulties with regard to expensive second-line drugs. Thais and other developing country citizens should have the same access to life-saving drugs. USTR should instead focus its efforts on persuading the pharmaceutical industry to lower its prices. We hope that under the new Obama Administration there will be a shift on access to medicines policy. Thailand's listing should not be linked in any way to acting within its rights.

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Q&A:

**USTR:** Please keep in mind that the CL issue was just one of many issues that we considered in raising and keeping Thailand on the PWL.

**AIDS Access Foundation:** Fine, but TRIPs-compliant actions should not even be considered.

**USTR:** The main concern with the CLs was non-transparency in how they were issued.

**AIDS Access Foundation:** We have plenty of documentation on negotiations between US pharmaceutical companies on pricing for the ARVs, but none of these negotiations resulted in



significant reductions in price. Abbott, for instance, refused to reduce prices until after Thailand issued its CL – then Abbott reduced its price for the developing world, but not for Thailand. Had Abbott done that for Thailand prior to the issuance of the CL, Thailand likely would not have issued the CL. We would be happy to share those documents with you. What other non-transparency issues are there?

**USPTO/USTR:** I don't believe those documents were available at the time the decisions were made, but rather became available afterwards. We have heard that it is unclear how the process works, and companies were surprised by the speed of some of the decisions that were made. Industry indicated that talks did take place beforehand, but said they had stalled and they did not realize that the government was going to issue the CL so soon.

*Pre-decisional and Deliberative, Internal DOC Only*

**2008 SPECIAL 301 TPSC MEETING**

**DATE:** Wednesday, April 7, 2010

**TIME:** 9:30 a.m.

**LOCATION:** USTR, Room 305

Non-Responsive



Non-Responsive



Non-Responsive



**THAILAND**

**BACKGROUND**

Exemption 5

Non-Responsive

Jean Kelly

---

**From:** Craig Allen  
**Sent:** Saturday, December 04, 2010 11:36 AM  
**To:** Jean Kelly  
**Cc:** Jeffrey Dutton; Bill Golike  
**Subject:** RE: Comments/Clearance requested: Draft briefing paper for Thai meeting with DUS O'Neill on Dec 8

Exemption 5



**MEETING WITH THAI COMMERCE MINISTRY  
DEPUTY PERMANENT SECRETARY RACHANE**

Exemption 5

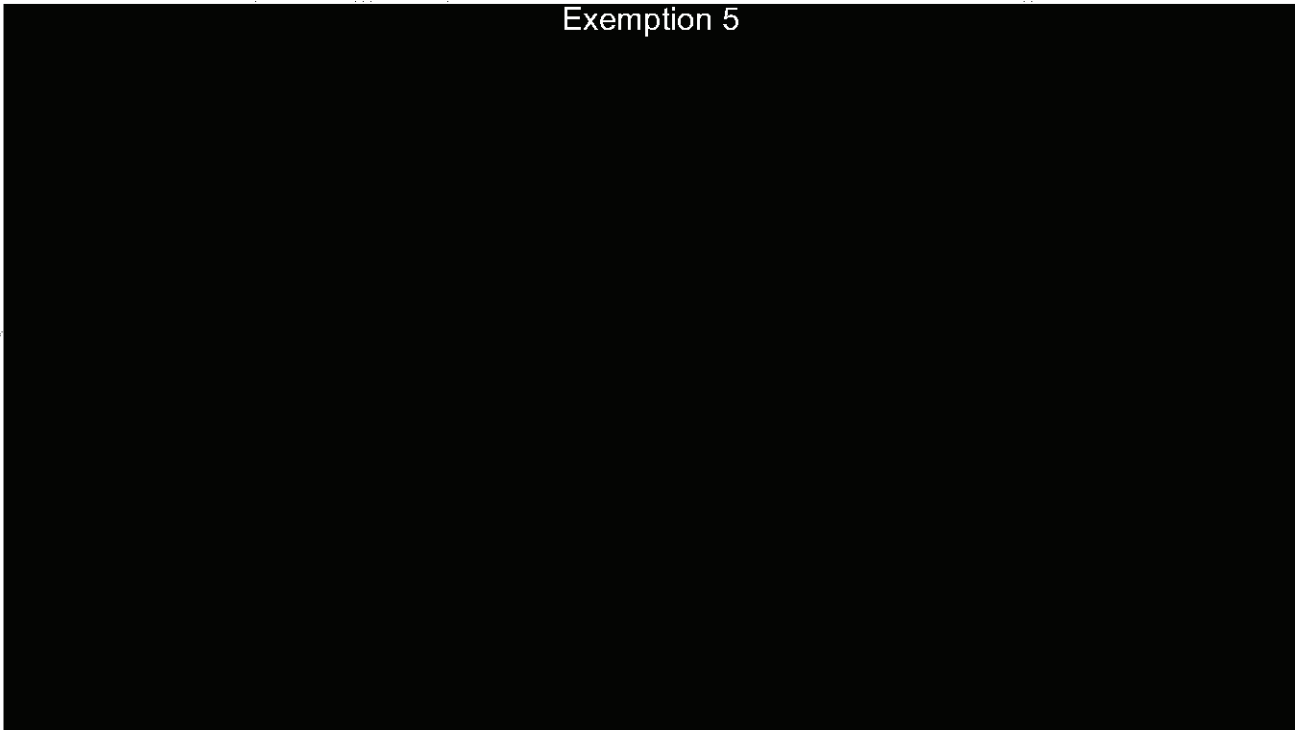








Exemption 5



**TALKING POINTS**

Exemption 5



Exemption 5







**MEETING WITH THAI COMMERCE MINISTRY  
DEPUTY PERMANENT SECRETARY RACHANE**

Exemption 5



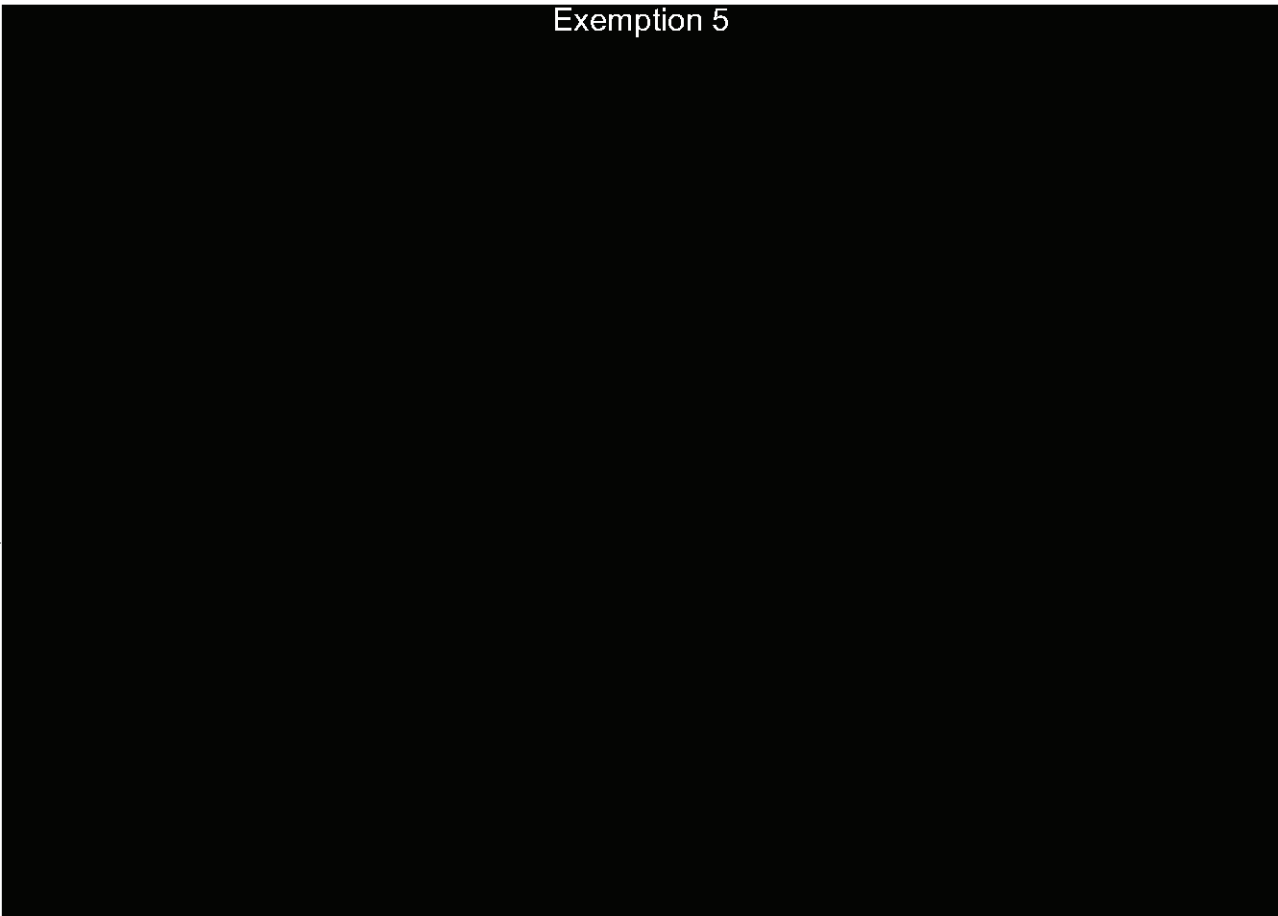
**SENSITIVE AND PRIVILEGED: DO NOT COPY WITHOUT PERMISSION**





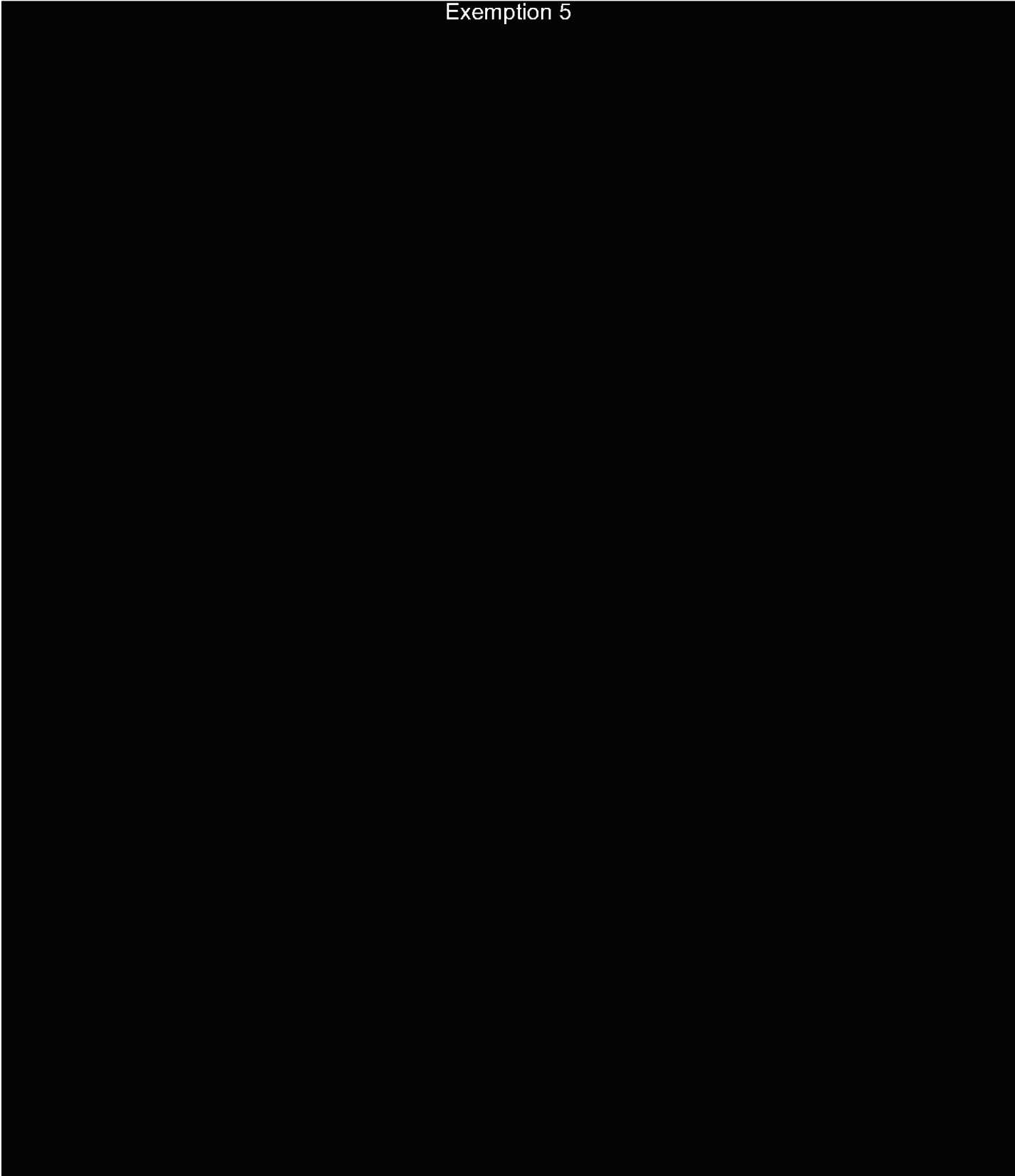


Exemption 5



**TALKING POINTS**

Exemption 5



Exemption 5



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**MEETING WITH THAI MINISTER OF COMMERCE PORNTIVA**

Exemption 5



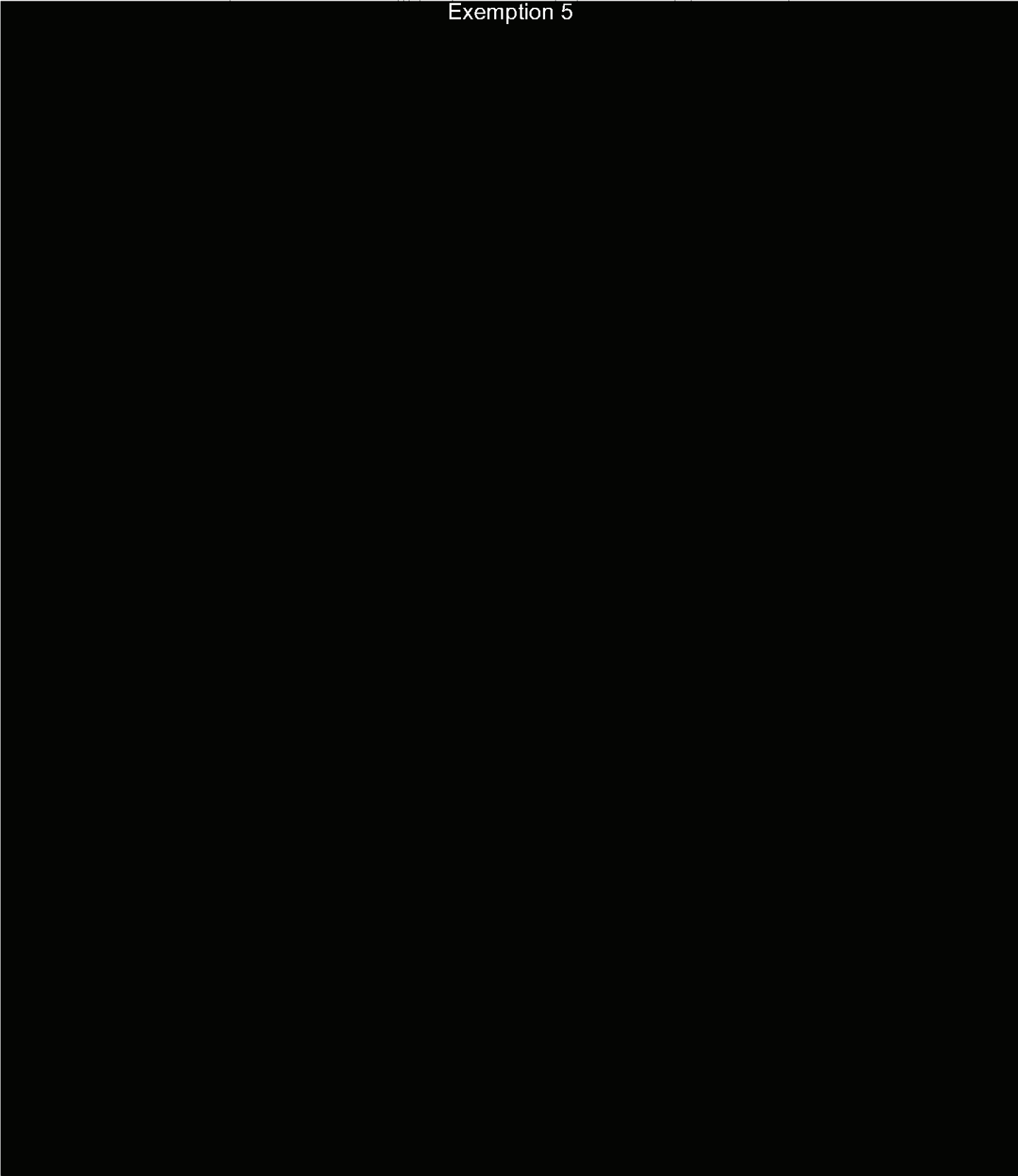




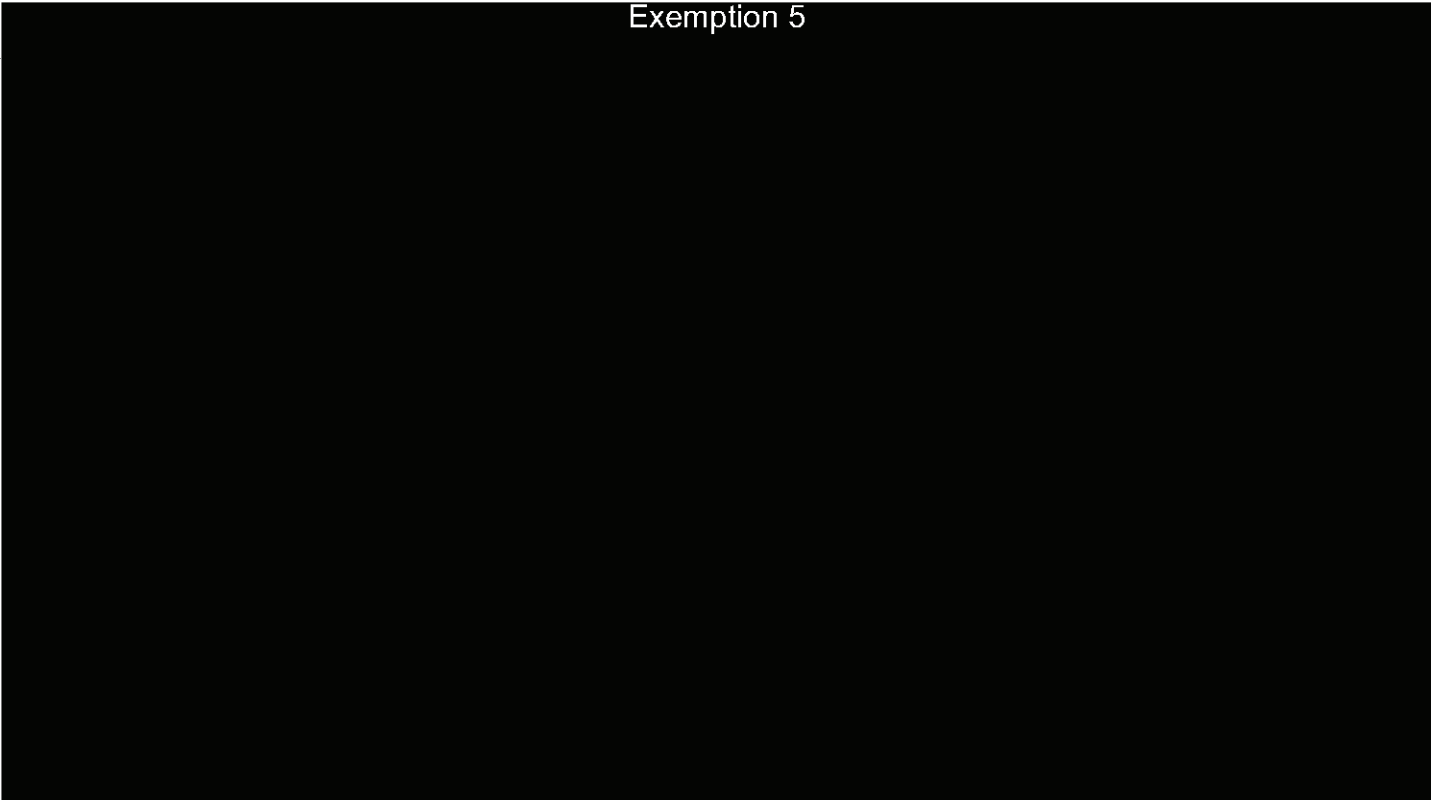


**TALKING POINTS**

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Exemption 5



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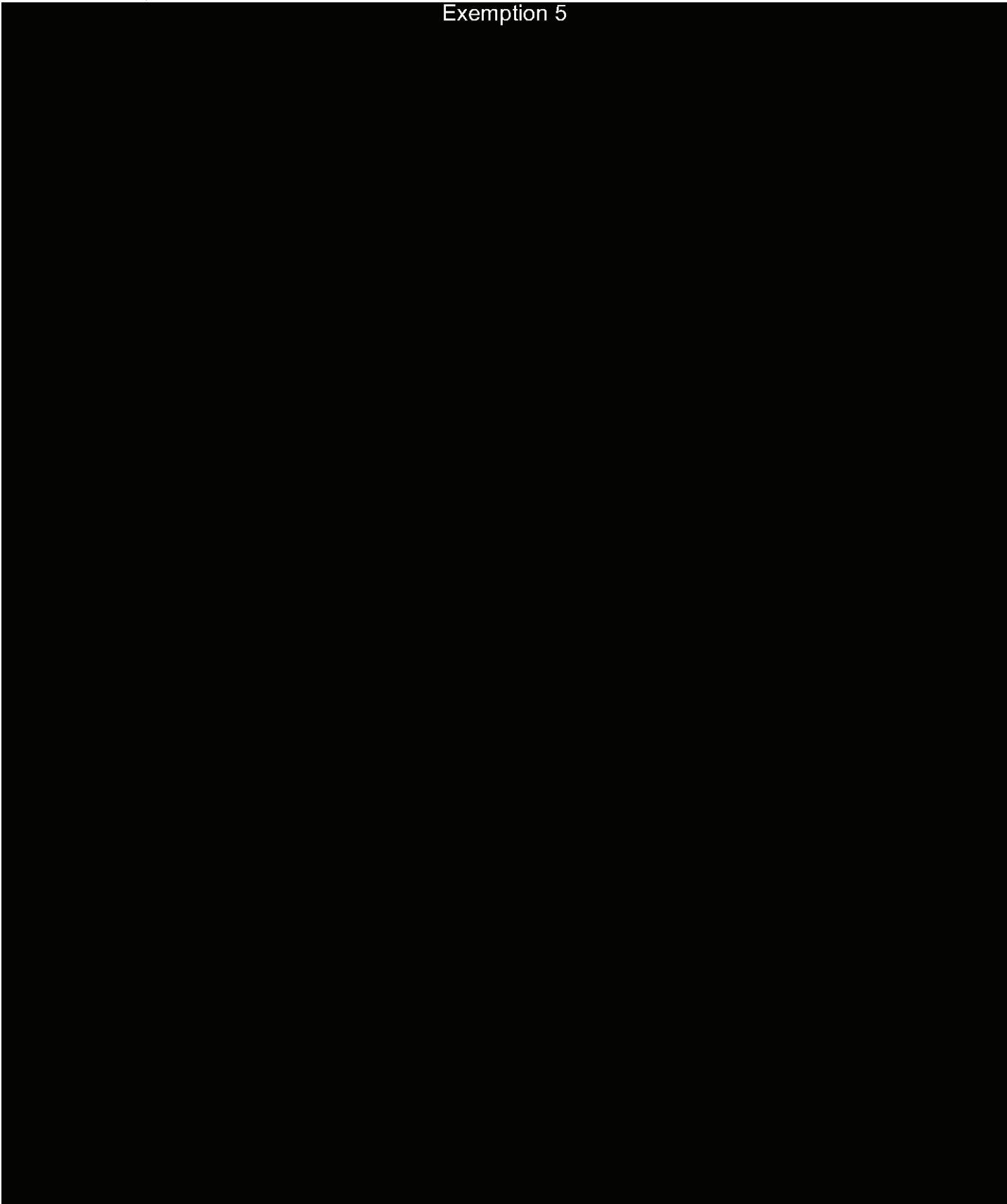
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Exemption 5



Please let me know if you have any questions about the roundtable.

Thanks.

Jean

Jean Kelly

Thailand desk officer



Office of the Pacific Basin  
International Trade Administration  
U.S. Department of Commerce  
tel: 202-482-3448  
fax: 202-482-3316  
[Jean.Kelly@trade.gov](mailto:Jean.Kelly@trade.gov)

**Thailand's Fourteen Points of Clarification: The US National Trade Estimate Report on Foreign Trade Barriers**

Exemption 5






















Emily  
Arakaki/MAS/ITA/USDOC  
08/07/2009 12:36 PM

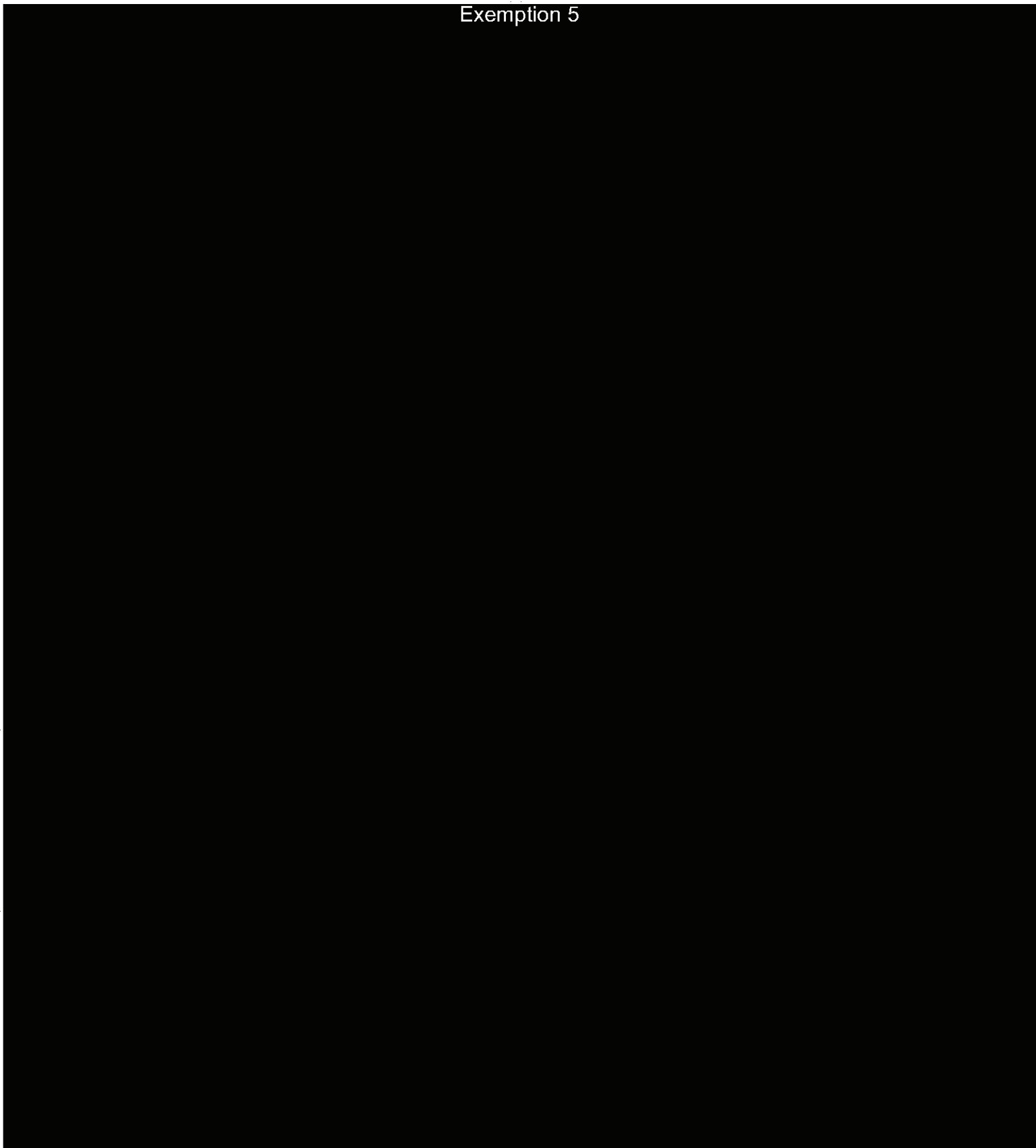
To: Jean Kelly/MAC/ITA/USDOC@USDOC  
cc: Molly Torsen/MAC/ITA/USDOC@USDOC  
bcc:

Subject: Re: Thai CL case: time to close it? 

Exemption 5



Exemption 5



Jennie Ness is on vacation this month, but I can ask our SCO in Bangkok if she's heard anything lately.

Thanks.

Jean

Jean Kelly  
Thailand desk officer  
Office of the Pacific Basin  
International Trade Administration  
U.S. Department of Commerce  
tel: 202-482-3448  
fax: 202-482-3316

----- Forwarded by Jean Kelly/MAC/ITA/USDOC on 08/05/2009 02:13 PM -----



John Hellmann  
<jhellmann@brooksbowerasia.com>

05/07/2009 03:21 PM

To: Jean Kelly <Jean\_Kelly@ita.doc.gov>  
cc: Julie Sheetz <jsheetz@brooksbowerasia.com>, Ernie Bower <ebower@brooksbowerasia.com>  
Subject: RE: Question Regarding Thai CL> John Hellmann>  
BrooksBowerAsia

Hi Jean,

Thank you for getting back to me on this. I'm adding Julie and Ernie to this chain so they keep abreast of the issue as well.

I've reached out to a number of people in govt., including yourself, and have only received one response from Jennie Ness at the US Embassy in BKK. I thought you would find her response interesting.

When you hear from your colleague on the ground, please let us know!

Best wishes,

John Hellmann

---

**John Hellmann | Associate Director**  
**BrooksBowerAsia**

1030 Wisconsin Avenue | Washington, DC 20007

Office: 202.338.3250 | Cell: 202.446.6860 | Fax: 202.338.3230

[JHellmann@brooksbowerasia.com](mailto:JHellmann@brooksbowerasia.com) | [www.brooksbowerasia.com](http://www.brooksbowerasia.com)

Dear John,

There's been quite a bit of press concerning the Special 301 announcement, and I believe this is just one reporter's attempt to look at it from another angle (and rehash a popular story). I have not, myself, heard anything from the Royal Thai Government to lend any credence to this story. I have seen the Deputy Minister of Commerce, all of the leadership of the Department of Intellectual Property, and the Americas team from the Ministry of Foreign Affairs in the last week and know that they would have raised this issue if there had been any policy announcement.

In addition, the Ministry of Public Health is continuing to make announcements that it is considering generic options for a number of drugs under patent. The CL Committee has been in price negotiations with three drug manufacturers (of oncological biologics) over the past two months. Last week, MOPH announced that the negotiations were going poorly and that they were off to visit an Indian generic supplier to see what deals they could get there. We are monitoring this situation and do not believe there's any reason for concern at the moment. The MOPH announcements have only been made in Thai on the MOPH website, and they feel more like sabre rattling than real news.

Please let me know what you're hearing from DC. Thanks.

Best Regards,  
Jennie

Jennie Ness  
Regional Intellectual Property Attache for ASEAN  
U.S. Patent and Trademark Office  
U.S. Embassy Bangkok  
Commercial Section  
Room 302, GPF Witthayu Tower A,  
93/1 Wireless Road,  
Bangkok, 10330 Thailand  
Tel: 66-2-205-5913  
Fax: 66-2-255-2915  
E-mail: [jennie.ness@mail.doc.gov](mailto:jennie.ness@mail.doc.gov)

**From:** Jean Kelly [mailto:[Jean\\_Kelly@ita.doc.gov](mailto:Jean_Kelly@ita.doc.gov)]  
**Sent:** Thursday, May 07, 2009 2:44 PM  
**To:** John Hellmann  
**Subject:** Re: Question Regarding Thai CL> John Hellmann> BrooksBowerAsia

Hi John-

I'm sorry to say that I don't know whether or not this press report is accurate, but I've asked my colleague in Bangkok for an update.

I'll let you know when I hear anything.

Thanks.

Jean

Jean Kelly  
Thailand desk officer  
Office of the Pacific Basin  
International Trade Administration  
U.S. Department of Commerce  
tel: 202-482-3448  
fax: 202-482-3316

John Hellmann <jhellmann@brooksbowerasia.com>

To: "jean\_kelly@ita.doc.gov" <jean\_kelly@ita.doc.gov>

05/06/2009 04:21 PM

cc  
Subject: Question Regarding Thai CL > John Hellmann > BrooksBowerAsia

Dear Jean:

John Hellmann here at BrooksBowerAsia. I hope this note finds you well.

I just wanted to contact you regarding the article below. To the best of your knowledge is this information accurate? We are wondering because we haven't heard anything from our networks in Bangkok indicating that Abhisit intends to "cave" to US pressure by not extending compulsory licensing due to the PWL.

If you could get back to me with your thoughts/what you've been hearing on this issue at your earliest convenience, it would be greatly appreciated.

Best wishes,

John Hellmann

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**John Hellmann | Associate Director  
BrooksBowerAsia**

1030 Wisconsin Avenue | Washington, DC 20007

Office: 202.338.3250 | Cell: 202.446.6860 | Fax: 202.338.3230

[JHellmann@brooksbowerasia.com](mailto:JHellmann@brooksbowerasia.com) | [www.brooksbowerasia.com](http://www.brooksbowerasia.com)

**Government Not to Extend Compulsory Licensing Policy**

*BBC Monitoring Asia Pacific, May 2*

Thailand has caved in to US pressure and will not extend the compulsory licensing (CL) policy to cover other badly needed life-saving drugs for the poor.

The government will not extend the policy as the Obama administration has maintained Thailand on the Priority Watch List of countries to be closely monitored for intellectual property rights violations.

Public Health Minister Witthaya Kaewparadai yesterday said he would not extend the CL policy to bypass more drug patents because there had been no such request from civil groups and the impact of the CL policy on trade and other sectors was huge.

"I can assure you that Thai people will continue to have access to cheaper medicines through an alternative policy," he said.

Mr Witthaya said he did not have any plan to revoke the previous CL policy on Aids, cancer and heart drugs announced by the post-coup Surayud government.

The issue needed to be discussed by all the involved sectors and agencies as well as the National Health Security Office.

Mr Witthaya plans to meet representatives of multi-national drug makers to formally explain the government stance on compulsory licences.

Jiraporn Limpananont, Foundation for Consumers chairman, urged Deputy Commerce Minister Alongkorn Ponlaboot to reveal the details of the deals that were struck with the United States Trade Representative (USTR) during his trip to Washington in December.

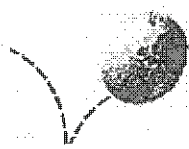
"Any agreements the Thai government has committed to with the US for trade benefits could end up hurting local pharmaceutical development and the public's right to cheaper generic versions of expensive patented medicines," she said.

Under the Special 301 Act, Washington can take trade action or seek dispute settlements against countries on either the Priority Watch List or the Watch List.


Public health and consumer groups have expressed disappointment over the Obama administration's pro-pharma industry policies.

Robert Weissmann, director of the Essential Action's access to medicine project, said USTR action against Thailand's effort to lower drug prices and extend access to life-saving medicines via compulsory licences was "deeply embarrassing".

Brook Baker, a law expert at Northeastern University, said the latest USTR report reflected the strong arm of corporate power, especially the drug industry, over US trade policy. "The Annual Special 301 Report is a cut and paste job from industry's submissions and is virtually indistinguishable from those issued for eight years by the Bush administration. Poor people desperately need access to life-saving and life-enhancing medicines and countries need intellectual property rules that prioritise public health, not just obscene corporate profits," he said.



Michael  
Hogge/MAC/ITA/USDOC  
08/20/2009 11:46 AM

To Jean Kelly/MAC/ITA/USDOC@USDOC  
cc Bill Golike/MAC/ITA/USDOC@USDOC, Kent  
Stauffer/MAC/ITA/USDOC@USDOC  
bcc  
Subject Re: Your question about the Thai CL case 

Thanks, Jean.

Michael Hogge  
International Trade Specialist  
Market Access and Compliance  
International Trade Administration  
U.S. Department of Commerce  
Tel. (202) 482-1405  
Fax (202) 482-3316

Jean Kelly/MAC/ITA/USDOC

Jean Kelly/MAC/ITA/USDOC  
08/20/2009 11:45 AM

To Michael Hogge/MAC/ITA/USDOC@USDOC  
cc Bill Golike/MAC/ITA/USDOC@USDOC, Kent Stauffer  
Subject Your question about the Thai CL case

Michael-

Exemption 5



Please let me know if you need any additional information.

Thanks.

Jean

Jean Kelly  
Thailand desk officer  
Office of the Pacific Basin  
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U.S. Department of Commerce  
tel: 202-482-3448



fax: 202-482-3316

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Jean Kelly/MAC/ITA/USDOC

05/07/2009 04:55 PM

To Jennie Ness/THAILAND/USFCS/USDOC@USDOC

cc Cynthia Griffin  
Greene/THAILAND/USFCS/USDOC@USDOC, James  
Golsen/THAILAND/USFCS/USDOC@USDOC, Bill

bcc Jean Kelly/MAC/ITA/USDOC

Subject Request re Thai complaints re NTE's IPR section

Exemption 5





**Thailand's Fourteen Points of Clarification: The US National Trade Estimate Report on Foreign Trade Barriers**

Exemption 5


















Jean Kelly/MAC/ITA/USDOC  
04/14/2009 09:24 AM

To Molly Torsen/MAC/ITA/USDOC@USDOC  
cc  
bcc Jean Kelly  
Subject Draft demarche for Thailand 

Molly-

Exemption 5














Jennie  
Ness/THAILAND/USFCS/US  
DOC

08/09/2009 03:15 PM

To: Jean Kelly/MAC/ITA/USDOC@USDOC, Cynthia  
Griffin/THAILAND/USFCS/USDOC@USDOC  
cc: Francis Peters/THAILAND/USFCS/USDOC@USDOC, Bill  
Golike/MAC/ITA/USDOC@USDOC  
bcc:

Subject: Re: Thai Compulsory Licensing Case: time to close it? 

Exemption 5



Cynthia- I know that Jennie is on leave this month, but we would appreciate your thoughts.

Thanks.



Jean

Jean Kelly

Thailand desk officer

Office of the Pacific Basin

International Trade Administration

U.S. Department of Commerce

tel: 202-482-3448

fax: 202-482-3316

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3/11/09

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1/6/10

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2/12/10

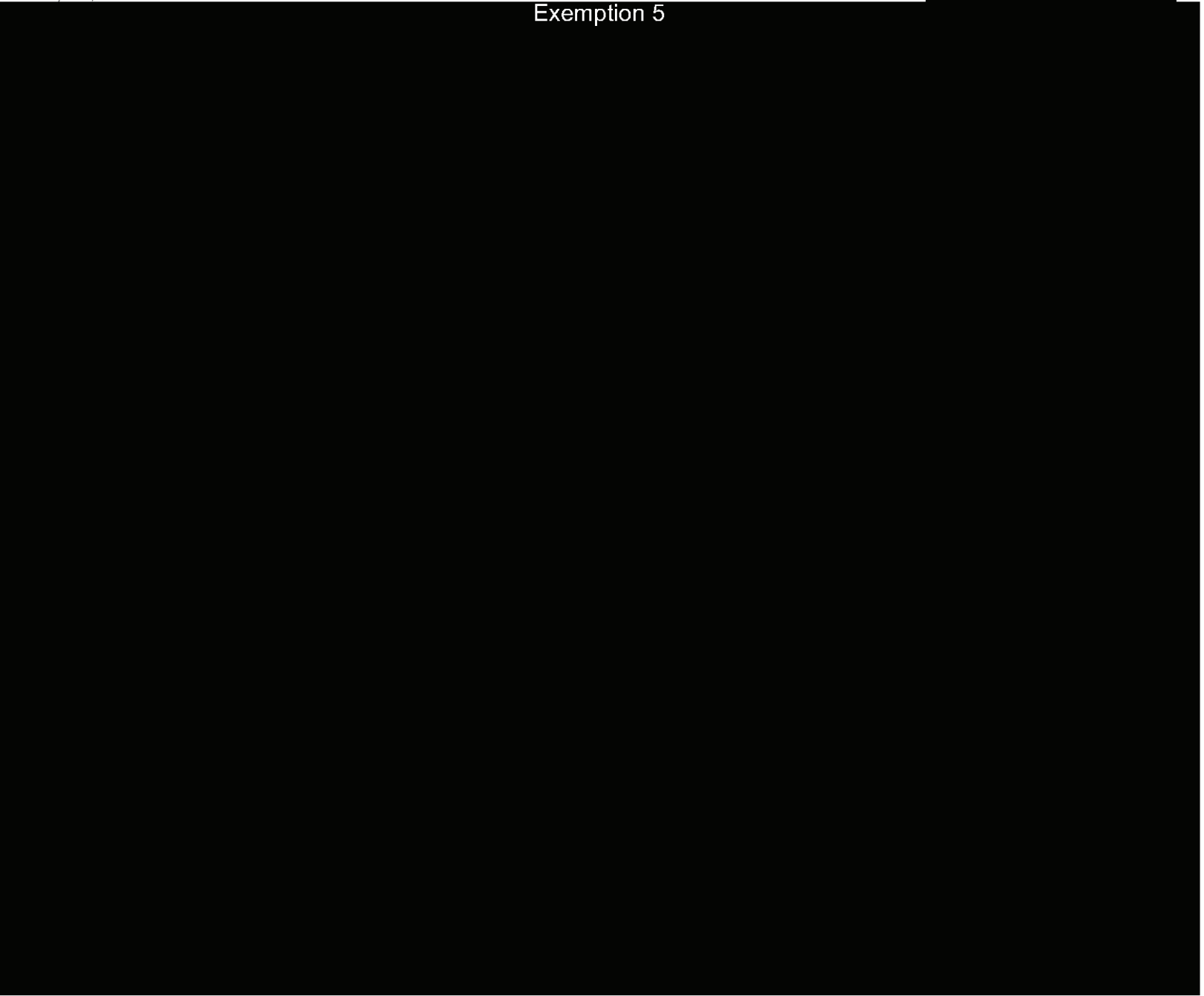
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7/12/10

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