Keppel, Mel J. EOP/USTR

From: Kuzmuk, Chris <CKuzmuk@phrma.org>
Sent: Friday, February 23, 2018 9:31 AM
To: Ehlers, Karl R. EOP/USTR; Lee, Daniel E. EOP/USTR; Brown, Christine P. EOP/USTR; Baumgarten, Ronald J. EOP/USTR
Cc: Andrade, Andres EOP/USTR; Shields, Janice F. EOP/USTR
Subject: [EXTERNAL] RE: ASEAN Issues

Great, thanks. I'll confirm Monday who will be along with me. Have a great weekend!

CK

Chris Kuzmuk, PhRMA, 202-(b) (6) (direct), 703(b) (6) (cell), ckuzmuk@phrma.org

---

From: Ehlers, Karl R. EOP/USTR [mailto:Karl_R._Ehlers@ustr.eop.gov]
Sent: Friday, February 23, 2018 9:22 AM
To: Kuzmuk, Chris <CKuzmuk@phrma.org>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>; Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>; Baumgarten, Ronald J. EOP/USTR <Ronald_Baumgarten@ustr.eop.gov>
Cc: Andrade, Andres EOP/USTR <andres.andrade@ustr.eop.gov>; Shields, Janice F. EOP/USTR <Janice_Shields@ustr.eop.gov>
Subject: RE: ASEAN Issues

Chris, thanks. 11 works on Wed. See you then.

From: Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
Sent: Friday, February 23, 2018 9:18 AM
To: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>; Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>
Subject: [EXTERNAL] RE: ASEAN Issues

Wednesday would work great. How about 10 or 11am?

CK

Chris Kuzmuk, PhRMA, 202(b) (5), (direct), 703-(b) (5), (cell), ckuzmuk@phrma.org

---

From: Ehlers, Karl R. EOP/USTR [mailto:Karl_R._Ehlers@ustr.eop.gov]
Sent: Friday, February 23, 2018 8:10 AM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>; Kuzmuk, Chris <CKuzmuk@phrma.org>; Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>
Subject: RE: ASEAN Issues

Chris,
It would be great to catch up and we will keep Daniel up to date.
Wed is best for me. Are there times that work well for you?
Best, Karl

From: Lee, Daniel E. EOP/USTR
Sent: Thursday, February 22, 2018 8:20 PM
To: Kuzmuk, Chris <CKuzmuk@phrma.org>; Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Subject: RE: ASEAN Issues

Sorry that I'll miss this. Am in Papua New Guinea for APEC, but will be at the PhRMA Special 301 briefing on 3/7.

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative
for Innovation and Intellectual Property
Office of the U.S. Trade Representative (USTR)
daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

From: Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
Sent: Thursday, February 22, 2018 3:31 PM
To: Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Subject: [EXTERNAL] RE: ASEAN Issues

If you and Karl are around, would be great to meet next week. I (along with the Chamber and other members) are headed out to the region on March 3, so would like to connect beforehand.

Would sometime Tuesday/Wednesday work?

CK

Chris Kuzmuk, PhRMA, 202-835-3493 (direct), 703-598-9412 (cell), ckuzmuk@phrma.org

---

From: Brown, Christine P. EOP/USTR [mailto:Christine_P_Brown@ustr.eop.gov]
Sent: Thursday, February 22, 2018 3:26 PM
To: Kuzmuk, Chris <CKuzmuk@phrma.org>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Subject: RE: ASEAN Issues

Chris,

Good to hear from you. Happy to meet with you next week, but Daniel is on travel and won't be back until the week of March 5. Can we wait until he returns?

Thanks,
Christine

Christine Brown, USTR
202-395-9472

From: Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
Sent: Thursday, February 22, 2018 3:25 PM
To: Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Subject: [EXTERNAL] ASEAN Issues

Christine, Karl, Daniel,

Hope you're all well. Karl, missed you at the Chamber this morning – was a good discussion with Diane though!

Do you all have time next week to meet on ASEAN? Would love to touch base on Indonesia and Malaysia again before we head out to the region the following week. I would look to bring in a few members.

Please let me know when may work – we can be flexible.

CK

Chris Kuzmuk
PhRMA
Associate Vice President, International Affairs
950 F Street, NW
Washington, DC 20005
202-(b) (6) (direct)
703-(b) (cell)
ckuzmuk@phrma.org

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Keppel, Mel J. EOP/USTR

From: Kuzmuk, Chris <CKuzmuk@phrma.org>
Sent: Thursday, February 8, 2018 2:11 PM
To: Lee, Daniel E. EOP/USTR; Moore, Chris
Subject: [EXTERNAL] RE: issues in SE Asia

Daniel,

Happy (very belated) new year!

Yes, would love to talk SE Asia and happy to organize something here at our offices. That being said, we are planning a SP 301 briefing, that Chris M. is leading. Not sure if there is a date set yet, so will defer to him. In that though, we will certainly be touching on Indonesia and Malaysia, amongst other ASEAN countries perhaps.

Perhaps we see where we are following that SP 301 brief, and if we think valuable to schedule something additional or more in depth, we can easily do so?

CK

Chris Kuzmuk, PhRMA, 202-(b) (6) (direct), 703-(b) (6) (cell), ckuzmuk@phrma.org

---

From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Thursday, February 8, 2018 1:59 PM
To: Moore, Chris <CMoore@phrma.org>; Kuzmuk, Chris <CKuzmuk@phrma.org>
Subject: issues in SE Asia

Chris and Chris,

How are you doing?

Over the last few weeks, some of your member companies have been coming in on specific issues on specific countries in Southeast Asia. I'm wondering if it would be helpful to have a meeting like we did a few months ago to discuss developments across Southeast Asia.

Please let me know if you are interested. Not sure if PhRMA is already planning to do a multi-hour briefing for the Special 301 interagency sub-committee already, so don't want to be redundant.

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative
for Innovation and Intellectual Property
Office of the U.S. Trade Representative (USTR)
daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

Keppel, Mel J. EOP/USTR

From: Moore, Chris <CMoore@phrma.org>
Sent: Thursday, January 18, 2018 5:00 PM
To: Lee, Daniel E. EOP/USTR
Subject: [EXTERNAL] RE: Malaysia

202(b) (6)

-----Original Message-----
From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Thursday, January 18, 2018 4:59 PM
To: Moore, Chris <CMoore@phrma.org>; Kuzmuk, Chris <CKuzmuk@phrma.org>
Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Subject: RE: Malaysia

Chris,

What is the best number to reach you at?

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property Office of the U.S. Trade Representative (USTR) daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

-----Original Message-----
From: Moore, Chris [mailto:CMoore@phrma.org]
Sent: Thursday, January 18, 2018 2:30 PM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>; Kuzmuk, Chris <CKuzmuk@phrma.org>
Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Subject: [EXTERNAL] RE: Malaysia

Works great. Look forward to speaking with you then. Best,

C.

-----Original Message-----
From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Thursday, January 18, 2018 1:58 PM
To: Moore, Chris <CMoore@phrma.org>; Kuzmuk, Chris <CKuzmuk@phrma.org>
Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Subject: RE: Malaysia

Hi Chris,

Would 5:00pm today work?

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property Office of the U.S. Trade Representative (USTR) daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

-----Original Message-----
From: Moore, Chris [mailto:CMoore@phrma.org]
Sent: Thursday, January 18, 2018 12:08 PM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>; Kuzmuk, Chris <CKuzmuk@phrma.org>
Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Subject: [EXTERNAL] RE: Malaysia

Hi Daniel,

A couple options...

We could talk this evening at 8:00 PM. Know that would not be ideal, but would enable Chris K. to participate. He is over in Asia now). Or, we could talk this afternoon. I'm available between 2:30 and 3 or between 4 and 5:30.

If none of those times work for you, also happy to talk tomorrow morning.

Let me know what works best on your end. Many thanks,

Chris

-----Original Message-----
From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Thursday, January 18, 2018 11:22 AM
To: Moore, Chris <CMoore@phrma.org>; Kuzmuk, Chris <CKuzmuk@phrma.org>
Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Subject: RE: Malaysia

Hi Chris,

Would sometime this afternoon or tomorrow morning work?

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property Office of the U.S. Trade Representative (USTR) daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

-----Original Message-----
From: Moore, Chris [mailto:CMoore@phrma.org]
Sent: Wednesday, January 17, 2018 7:48 PM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>; Kuzmuk, Chris <CKuzmuk@phrma.org>
Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Subject: [EXTERNAL] RE: Malaysia

Hi Daniel and Karl,

Great that you will be in Malaysia. Chris K. is on travel in the region this week, but would be good for the four of us to talk by phone when you can.

Appreciate if you could advise times that work best for you. We will do our best to align on this end.

Many thanks,

Chris

-----Original Message-----
From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Wednesday, January 17, 2018 5:54 PM
To: Moore, Chris <CMoore@phrma.org>; Kuzmuk, Chris <CKuzmuk@phrma.org>
Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Subject: Malaysia

Hi Chris and Chris,

Karl and I are planning to make a stop in Malaysia as part of a broader trip to the region next week. Just wondering if you all had any updates to share on recent developments. If a quick phone call would be better, let us know.

Also, would be good to touch base on Australia and Indonesia after I get back.

Thanks.

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property Office of the U.S. Trade Representative (USTR) daniel_lee@ustr.eop.gov
(202) 395-9549

Keppel, Mel J. EOP/USTR

From: Lee, Daniel E. EOP/USTR
Sent: Tuesday, October 3, 2017 5:53 PM
To: Kuzmuk, Chris
Cc: Brown, Christine P. EOP/USTR; Ehlers, Karl R. EOP/USTR; Prado, Marta M. EOP/USTR; Olson, Christina EOP/USTR
Subject: RE: checking in on SE pharmaceutical issues

Thanks, See you all tomorrow!

Best,

Daniel

--
Daniel Lee
Office of the U.S. Trade Representative (USTR)
daniel_lee@ustr.eop.gov
(202) 395-9549

-----Original Message-----
From: Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
Sent: Tuesday, October 3, 2017 4:28 PM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>; Olson, Christina EOP/USTR <Christina_Olson@ustr.eop.gov>
Subject: [EXTERNAL] RE: checking in on SE pharmaceutical issues

Daniel,

Thanks. Happy to start with Vietnam and Malaysia. Group will be as follows:

Chris Kuzmuk, PhRMA
Chris Moore, PhRMA
Ruben Duran, PhRMA
Amey Sutkowski, PhRMA (likely)
Megan Falkenhan, GSK
Doug Goudie, Pfizer
Laurel Vogelsang, Merck

Thanks,

CK

Chris Kuzmuk, PhRMA, 202-(b) (6) (direct), 703(b) (6) cell), ckuzmuk@phrma.org

-----Original Message-----
From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Tuesday, October 03, 2017 2:58 PM

To: Kuzmuk, Chris
Cc: Brown, Christine P. EOP/USTR; Ehlers, Karl R. EOP/USTR; Prado, Marta M. EOP/USTR; Olson, Christina EOP/USTR
Subject: RE: checking in on SE pharmaceutical issues

Chris,

Just a reminder to let us know who all will be joining tomorrow. We would like to start with Vietnam and Malaysia, followed by the other countries. Thanks.

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property Office of the U.S. Trade Representative (USTR) daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

-----Original Message-----
From: Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
Sent: Wednesday, September 27, 2017 10:44 AM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>; Olson, Christina EOP/USTR <Christina_Olson@ustr.eop.gov>
Subject: [EXTERNAL] RE: checking in on SE pharmaceutical issues

Absolutely, will get you that Tuesday for sure.

Thanks,

CK

Chris Kuzmuk, PhRMA, 202(b) (6) (direct), 703(b) (6) (cell), ckuzmuk@phrma.org

-----Original Message-----
From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Wednesday, September 27, 2017 10:17 AM
To: Kuzmuk, Chris
Cc: Brown, Christine P. EOP/USTR; Ehlers, Karl R. EOP/USTR; Prado, Marta M. EOP/USTR; Olson, Christina EOP/USTR
Subject: RE: checking in on SE pharmaceutical issues

Great. Looking to hear from you on the exact list of people coming.

Best,

Daniel

--
Daniel Lee
Office of the U.S. Trade Representative (USTR) daniel_lee@ustr.eop.gov

(202) 395-9549

-----Original Message-----
From: Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
Sent: Wednesday, September 27, 2017 10:12 AM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>; Olson, Christina EOP/USTR <Christina_Olson@ustr.eop.gov>
Subject: [EXTERNAL] RE: checking in on SE pharmaceutical issues

Daniel,

That would work great. Will let you know who will attend on Tuesday, if that works.

CK

Chris Kuzmuk, PhRMA, 202-(b) (6) (direct), 703(b) (6) (cell), ckuzmuk@phrma.org

-----Original Message-----
From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Wednesday, September 27, 2017 9:56 AM
To: Kuzmuk, Chris
Cc: Brown, Christine P. EOP/USTR; Ehlers, Karl R. EOP/USTR; Prado, Marta M. EOP/USTR; Olson, Christina EOP/USTR
Subject: RE: checking in on SE pharmaceutical issues

Hi Chris,

How about 4:00pm next Wednesday at the USTR Annex? We'll block 1.5 hours.

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property Office of the U.S. Trade Representative (USTR) daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

-----Original Message-----
From: Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
Sent: Wednesday, September 27, 2017 9:07 AM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>; Olson, Christina EOP/USTR <Christina_Olson@ustr.eop.gov>
Subject: [EXTERNAL] RE: checking in on SE pharmaceutical issues

Daniel,

No worries, totally get the NAFTA take over! Absolutely want to set something up. Would next Wednesday at some point work for you all?

CK

Chris Kuzmuk, PhRMA, 202-(b) (6) (direct), 703-(b) (6) (cell), ckuzmuk@phrma.org

-----Original Message-----
From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Sunday, September 24, 2017 11:19 PM
To: Kuzmuk, Chris
Cc: Brown, Christine P. EOP/USTR; Ehlers, Karl R. EOP/USTR; Prado, Marta M. EOP/USTR; Olson, Christina EOP/USTR
Subject: RE: checking in on SE pharmaceutical issues

Hi Chris,

Sorry for the slow response. I got temporarily pulled in to help on NAFTA and am actually heading up to Ottawa tomorrow for the next negotiating round.

How would the week of 10/2 look for your members and you? Also, please let us know which countries you would like to discuss so that we can make sure we have the right people attending on our side.

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property Office of the U.S. Trade Representative (USTR) daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

-----Original Message-----
From: Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
Sent: Sunday, September 10, 2017 7:46 PM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>
Subject: RE: checking in on SE pharmaceutical issues

Daniel,

Welcome home. Would of course love to get together, but I'm literally en route to Seoul as we speak. Gone all week. Can we arrange something for the week of the 18th? Or, if you feel this is something more urgent, we can certainly arrange with members and I can have other PhRMA colleagues join and cover in my absence. Let me know.

CK

Chris Kuzmuk, PhRMA, 202-(b) (6) (direct), 703-(b) (6) (cell), ckuzmuk@phrma.org

-----Original Message-----
From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]

Sent: Sunday, September 10, 2017 5:16 PM
To: Kuzmuk, Chris
Cc: Brown, Christine P. EOP/USTR; Ehlers, Karl R. EOP/USTR; Prado, Marta M. EOP/USTR
Subject: checking in on SE pharmaceutical issues

Hi Chris,

I wanted to catch up with your members and you now that I'm back from Indonesia and Thailand. Could we meet sometime in the next week to discuss Indonesia (any non-Patent Law issues since I believe the US Chamber is doing something separately) and Thailand? Might be good to also touch base on Malaysia, Vietnam, and any other Southeast Asia countries, to the extent that there are concerns cropping up.

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property Office of the U.S. Trade Representative (USTR) daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

Keppel, Mel J. EOP/USTR

From: Lee, Daniel E. EOP/USTR
Sent: Thursday, April 5, 2018 10:12 AM
To: Kuzmuk, Chris
Cc: Prado, Marta M. EOP/USTR; Ehlers, Karl R. EOP/USTR; Baumgarten, Ronald J. EOP/USTR; Thanhauser, Bartholomew J. EOP/USTR; Catherine Hinckley; 'Matthew.LloydWatkins@pfizer.com'
Subject: RE: [EXTERNAL] RE: ASEAN Meeting?

Thanks. Talk to you soon.

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative
for Innovation and Intellectual Property
Office of the U.S. Trade Representative (USTR)
daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

From: Kuzmuk, Chris <CKuzmuk@phrma.org>
Sent: Thursday, April 5, 2018 9:39 AM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Baumgarten, Ronald J. EOP/USTR <Ronald_Baumgarten@ustr.eop.gov>; Thanhauser, Bartholomew J. EOP/USTR <Bartholomew_J_Thanhauser@ustr.eop.gov>; Catherine Hinckley <catherine.hinckley@gmail.com>; 'Matthew.LloydWatkins@pfizer.com' <Matthew.LloydWatkins@pfizer.com>
Subject: RE: [EXTERNAL] RE: ASEAN Meeting?

Adding Matthew and Catherine here. Let's use the following number. Look forward to speaking later.

Hope you feel better!

CK

Dial-In Information:

U.S.: 1-877-(b) (6)
Intl.: 1-206-(b) (6)
Other Countries: please click (b) (6)

Conference Code: (b) (6)

Chris Kuzmuk
Associate Vice President, International Affairs
950 F Street, NW
Washington, DC 20005
202(b) (6) (direct)

703(b) (6) (cell)
ckuzmuk@phrma.org

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From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Thursday, April 5, 2018 9:30 AM
To: Kuzmuk, Chris <CKuzmuk@phrma.org>
Cc: Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Baumgarten, Ronald J. EOP/USTR <Ronald_Baumgarten@ustr.eop.gov>; Thanhauser, Bartholomew J. EOP/USTR <Bartholomew_J_Thanhauser@ustr.eop.gov>
Subject: RE: [EXTERNAL] RE: ASEAN Meeting?

Chris,

If you have a dial-in number handy already, happy to use that. Thanks.

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative
for Innovation and Intellectual Property
Office of the U.S. Trade Representative (USTR)
daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

From: Kuzmuk, Chris <CKuzmuk@phrma.org>
Sent: Thursday, April 5, 2018 7:40 AM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Baumgarten, Ronald J. EOP/USTR <Ronald_Baumgarten@ustr.eop.gov>; Thanhauser, Bartholomew J. EOP/USTR <Bartholomew_J_Thanhauser@ustr.eop.gov>
Subject: Re: [EXTERNAL] RE: ASEAN Meeting?

Daniel,

Not a problem and completely understand. Happy to turn into a call. Can send around a number from my end as well if easier, just let me know.

CK

Chris Kuzmuk
PhRMA
(202)(b) (6) (office)
(703)(b) (6) (cell)

On Apr 5, 2018, at 7:18 AM, Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov> wrote:

Chris,

I'm not feeling well and will not be in the office today. But since we have the Thailand TIFA next week, it would be still good to connect this afternoon, if possible.

Could we convert our meeting into a conference call instead? If that works for you, I will send around a dial-in number.

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative
for Innovation and Intellectual Property
Office of the U.S. Trade Representative (USTR)
daniel_lee@ustr.eop.gov
(202) 395-9549

On Mar 30, 2018, at 9:10 AM, Kuzmuk, Chris <CKuzmuk@phrma.org> wrote:

> Daniel,
>
> 1PM Thursday works. Let's book it. I'll circle with a list of names on Tuesday. Have a great weekend.
>
> CK
>
> Chris Kuzmuk, PhRMA, 202(b) (6) (direct), 703-(b) (6) (cell), ckuzmuk@phrma.org
>
> ---
>
> **From:** Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
> **Sent:** Wednesday, March 28, 2018 6:33 PM
> **To:** Kuzmuk, Chris <CKuzmuk@phrma.org>
> **Cc:** Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Baumgarten, Ronald J. EOP/USTR <Ronald_Baumgarten@ustr.eop.gov>; Thanhauser, Bartholomew J. EOP/USTR <Bartholomew_J_Thanhauser@ustr.eop.gov>
> **Subject:** RE: ASEAN Meeting?
>
> Chris,
>
> How about 1:00 on Thursday (4/5)?
>
> Best,
>
> Daniel
>
> --
> Daniel Lee
> Deputy Assistant U.S. Trade Representative
> for Innovation and Intellectual Property
> Office of the U.S. Trade Representative (USTR)
> daniel_lee@ustr.eop.gov
> (202) 395-9549 tel
> (202) 395-3891 fax

From: Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
Sent: Wednesday, March 28, 2018 7:21 AM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Brown, Christine P. EOP/USTR <Christine_P_Brown@ustr.eop.gov>; Baumgarten, Ronald J. EOP/USTR <Ronald_Baumgarten@ustr.eop.gov>
Subject: [EXTERNAL] Re: ASEAN Meeting?

Sounds good Daniel, thanks. Let me know what works and we'll figure it out!

Christine - did not leave you out intentionally but heard an ugly rumor you were tired of Southeast Asia?! Just kidding!

CK

Chris Kuzmuk
PhRMA
(202) (b) (6) (office)
(703) (b) (6) (cell)

On Mar 27, 2018, at 6:18 PM, Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov> wrote:

> Hi Chris,
>
> Let us coordinate on our schedules and get back to you.
>
> Best,
>
> Daniel
>
> --
> Daniel Lee
> Deputy Assistant U.S. Trade Representative
> for Innovation and Intellectual Property
> Office of the U.S. Trade Representative (USTR)
> daniel_lee@ustr.eop.gov
> (202) 395-9549 tel
> (202) 395-3891 fax
>
> **From:** Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
> **Sent:** Monday, March 26, 2018 8:57 PM
> **To:** Prado, Marta M. EOP/USTR <Marta_M_Prado@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
> **Subject:** [EXTERNAL] ASEAN Meeting?
>
> Marta, Karl, Daniel,
>
> Hope you're all well – busy times I'm sure! Wanted to circle back and scheduling a time that we (myself and a few members) could come by and talk ASEAN markets. Would late next week work? That allows us to touch base in advance of the Thai TIFA meetings, but also certainly want to update on Vietnam, Philippines, Indonesia, and our quickly becoming favorite Malaysia.

Let me know when may work Wed, Thur, or Fri. and we'll work it on our end.

Thanks,

Chris

Chris Kuzmuk
PhRMA
Associate Vice President, International Affairs
950 F Street, NW
Washington, DC 20005
202-(b) (6) (direct)
703-(b) (6) (cell)
ckuzmuk@phrma.org

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Keppel, Mel J. EOP/USTR

From: Ehlers, Karl R. EOP/USTR
Sent: Wednesday, October 25, 2017 10:44 AM
To: Kuzmuk, Chris
Cc: Duran, Ruben; Sutkowski, Amey; Lee, Daniel E. EOP/USTR; Brown, Christine P. EOP/USTR
Subject: Re: [EXTERNAL] RE: Malaysia Contact?

Chris
I think i emailed his business card and Firdaus's in the original email, which should have all of their respective contact info, if you check the attachment. if that doesnt work Christine will be able to get you the info. I think his colleague Firdaus cell is (b) (6)
Best, Karl

Sent from my iPhone

On Oct 25, 2017, at 10:35 AM, Kuzmuk, Chris <CKuzmuk@phrma.org> wrote:

> Karl,
>
> We have attempted to email Hairil a few times, but with no luck. Would you have a phone number so that I can call?
>
> Thanks!
>
> CK
>
> Chris Kuzmuk, PhRMA, 202(b) (6) (direct), 703-(b) (6) cell), ckuzmuk@phrma.org

---

From: Ehlers, Karl R. EOP/USTR [mailto:Karl_R._Ehlers@ustr.eop.gov]
Sent: Thursday, October 05, 2017 4:04 PM
To: Kuzmuk, Chris
Cc: Duran, Ruben; Sutkowski, Amey; Lee, Daniel E. EOP/USTR
Subject: RE: Malaysia Contact?

Chris, as always it's great to catch up on your issues and concerns.
Regarding Malaysia, please see attached from my card file, for both Hairil and Firdaus. Hairil has a general email address listed, but his direct email is (b) (6) gov.my and I would use that in reaching out rather than the (b) (6) email address listed on his card.
I would email them both, recognizing that you will probably hear back from Firdaus. If you don't, please let me know and we can double track.
They are quite familiar with the issue you would like to talk about.
All the best, Karl

From: Kuzmuk, Chris [mailto:CKuzmuk@phrma.org]
Sent: Thursday, October 5, 2017 3:52 PM
To: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Cc: Duran, Ruben <RDuran@phrma.org>; Sutkowski, Amey <ASutkowski@phrma.org>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Subject: [EXTERNAL] Malaysia Contact?

Karl,

Great seeing you all yesterday. Wanted to follow-up with you on a good contact at the Malaysian Embassy, as they've been a bit unresponsive to us at this point! Would appreciate any direction.

Thanks,

CK

Chris Kuzmuk
PhRMA
Associate Vice President, International Affairs
950 F Street, NW
Washington, DC 20005
202-(b) (6) (direct)
703-(b) (6) (cell)
ckuzmuk@phrma.org

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Keppel, Mel J. EOP/USTR

From: Lee, Daniel E. EOP/USTR
Sent: Friday, January 19, 2018 9:59 AM
To: Michael Pascual
Subject: Accepted: [EXTERNAL] Re: Thank you and follow-up, Gilead Sciences

Keppel, Mel J. EOP/USTR

From: Barry Featherman <Barry.Featherman@gilead.com>
Sent: Tuesday, November 7, 2017 10:38 PM
To: Ehlers, Karl R. EOP/USTR; Lee, Daniel E. EOP/USTR; Kendall, Elizabeth L. EOP/USTR
Subject: [EXTERNAL] Fwd: Malaysian agreement to import generic SOF

Follow Up Flag: Flag for follow up
Flag Status: Flagged

Dear Karl, Elizabeth and Daniel:

Please see below for recent press articles referring to Pharmaniaga's agreement with Pharco and DNDi on sofosvubir. The stated date of the agreement is July 26, 2017 for ten years. This seems problematic on two fronts: 1) this agreement pre-dates the Cabinet's decision to authorize the public use taking and 2) the public use taking is for a three-year duration yet the agreement is for ten years. Best, Barry

Malaysian drugmaker Pharmaniaga announced it entered into a collaboration with Pharco Pharmaceuticals and DNDi to promote access to affordable ravidasvir and sofosbuvir in Malaysia. The announcement notes that generic sofosbuvir importation is allowable under Section 84 of Malaysia's Patents Act 1983 and TRIPS. The agreement is a ten-year deal, effective July 26, 2017. Coverage follows from The Sun Daily, The Star, The Edge Markets and M2 Pharma.

***

Firm To Promote Access To Cheaper DAA Treatments
November 7, 2017
The Sun Daily (Malaysia) (sofosbuvir mention)

PETALING JAYA: Pharmaniaga Bhd's wholly owned subsidiary Pharmaniaga Logistics Sdn Bhd has entered into a collaboration agreement with Pharco Pharmaceuticals and the Drugs for Neglected Diseases initiative (DNDi).

In a filing with Bursa Malaysia today, Pharmaniaga said the collaboration aims to promote widespread access to affordable direct acting antivirals (DAAs) including ravidasvir in combination with sofosbuvir or other potential DAAs as safe, effective, affordable and pan-genotypic treatments for Hepatitis C in Malaysia. The collaboration follows the Health Ministry's recent announcement on the proposal to import effective generic drugs for treatment of Hepatitis C.

To recap, the ministry said in September that it expects to save RM49,500 in medication costs per patient per year in treating Hepatitis C-infected patients by switching to generic medicine, reflecting a 99% drop in cost per patient.

The ministry said it was paying RM50,000 per year for the patented drug for each patient while the generic drug costs only RM500 for a year's supply. The number of patients in Malaysia with Hepatitis C is estimated at 500,000.

***

Pharmaniaga To Promote Affordable Hep C Treatment In Malaysia
November 7, 2017
The Star (Malaysia) (sofosbuvir mention)

KUALA LUMPUR: Pharmaniaga Bhd will be collaborating with Pharco Pharmaceuticals and the Drugs for Neglected Diseases Initiative in an effort to promote affordable access to drug treatment of Hepatitis C in Malaysia.

Pharco Pharmaceuticals is a leading pharmaceutical distributor in Egypt, the Middle East and Africa while the Drugs for Neglected Diseases Initiative is a Swiss-based non-profit organisation that conducts research and development on drug treatment of neglected diseases.

According to a filing with Bursa Malaysia, Pharmaniaga unit Pharmaniaga Logistics Sdn Bhd entered into an agreement with the two parties to "promote widespread access to affordable direct acting antivirals (DAAs) including ravidasvir in combination with sofosbuvir or other potential DAAs as safe, effective, affordable and pan-genotypic treatments for Hepatitis C in Malaysia".

At 12.30pm, Pharmaniaga was trading unchanged at RM4 on low volume of shares traded.

***

Pharmaniaga Promotes Access To Affordable Generic Medicine
November 7, 2017
The Edge Markets (Malaysia) (sofosbuvir mention)

By Chong Jin Hun

KUALA LUMPUR (Nov 7): Pharmaniaga Bhd is collaborating with Pharco Pharmaceuticals and the Drugs for Neglected Diseases initiative to promote access to affordable generic drugs for Hepatitis C treatment.

In a statement to Bursa Malaysia today, Pharmaniaga said its wholly-owned subsidiary Pharmaniaga Logistics Sdn Bhd had today entered into the collaboration agreement with Pharco and Drugs for Neglected Diseases.

Pharmaniaga said the collaboration aims "to promote widespread access to affordable direct acting antivirals (DAAs), including ravidasvir in combination with sofosbuvir or other potential DAAs as safe, effective, affordable and pan-genotypic treatments for Hepatitis C in Malaysia, based on the terms and conditions stipulated therein".

At 12:30pm, Pharmaniaga shares settled at RM4 for a market value of RM1.04 billion. The stock was traded between RM4 and RM4.10 so far today.

***

Pharmaniaga, Pharco Pharmaceuticals And Drugs For Neglected Diseases Initiative Collaborate To Boost Access Hep C Treatment
November 7, 2017
M2 Pharma (sofosbuvir mention)

Malaysia’s largest listed integrated pharmaceutical group Pharmaniaga Bhd (KLSE: PHARMA) will collaborate with Pharco Pharmaceuticals and the Drugs for Neglected Diseases Initiative in a bid to boost affordable access to drug treatment of Hepatitis C in Malaysia, the company confirmed on Tuesday.

Pharco Pharmaceuticals a global provider of pharmaceutical products with a market presence in Egypt, the Middle East and Africa.

Meanwhile, the Drugs for Neglected Diseases Initiative is a Swiss-based non-profit organisation dedicated to investigating and developing drug treatment of neglected diseases.

According to the filing published by Bursa Malaysia, Pharmaniaga unit Pharmaniaga Logistics Sdn Bhd signed the agreement with the two parties to “promote widespread access to affordable direct acting antivirals (DAAs) including ravidasvir in combination with sofosbuvir or other potential DAAs as safe, effective, affordable and pan-genotypic treatments for Hepatitis C in Malaysia”.

Keppel, Mel J. EOP/USTR

From: Gregg Alton <Gregg.Alton@gilead.com>
Sent: Wednesday, January 17, 2018 2:26 PM
To: Griffin, Payne P. EOP/USTR
Cc: Kendall, Elizabeth L. EOP/USTR; Ehlers, Karl R. EOP/USTR; Lee, Daniel E. EOP/USTR
Subject: [EXTERNAL] Meeting request: Gilead Sciences, World Economic Forum, Davos

Mr. Griffin,

I write to request a meeting with Ambassador Lighthizer at the upcoming World Economic Forum in Davos, Switzerland. Robin Washington, our Chief Financial Officer and Executive Vice President, and I will be in Davos and would appreciate the opportunity to discuss Malaysia's recent issuance of a compulsory license on our hepatitis C medicine, sofosbuvir.

As we discussed last October, Malaysia's compulsory license represents a potential violation of TRIPS and other international patent protection regimes. The Malaysian government's action directly harms Gilead's business in Malaysia. We believe the Malaysian government's recent actions warrant U.S. government engagement.

Left unchecked, these decisions set a precedent and send a clear message to other countries, particularly in the region, that disrespect for American intellectual property will be tolerated by the U.S. government. Since the Malaysian compulsory license was announced, both the Chilean parliament and Colombian Ministry of Health have made similar announcements regarding hepatitis C medicines. We understand others in the biotech and pharmaceutical industry are closely following our issue due to their concern about the potential impact on their interests in Malaysia and other global markets.

We understand Davos is a busy time and appreciate your consideration of this request. Please let us know if you need any additional information.

Best Regards,
Gregg

Gregg Alton
Executive Vice President, Corporate and Medical Affairs
Gilead Sciences, Inc.
333 Lakeside Drive, Foster City, CA 94404
(650) (b) (6) (phone)
(650) (b) (6) (private fax)
galton@gilead.com

From: Kendall, Elizabeth L. EOP/USTR
To: Keppel, Mel J. EOP/USTR
Subject: FW: Following Up on Israel
Date: Friday, June 29, 2018 12:16:09 PM

-----Original Message-----
From: Joseph Damond <jdamond@bio.org>
Sent: Tuesday, December 12, 2017 3:55 PM
To: Kendall, Elizabeth L. EOP/USTR <Elizabeth_L_Kendall@ustr.eop.gov>
Subject: [EXTERNAL] RE: Following Up on Israel

While I have you Elizabeth (know you are busy!) two other quick things:

-- Saw Daniel Lee on Thursday with Gilead about Malaysia CL -- getting to be a big deal to industry, given that Gilead has tried to do everything right on pricing.
-- Letting the TRIPs moratorium on non-violation nullification and impairment cases expire would be a big deal for this industry -- in the sense that we'd greatly favor the expiration!

Hope all is well!

Joe

Joseph Damond
Executive Vice President, International Affairs
Biotechnology Innovation Organization (BIO)
(o) 202(b) (6)

Keppel, Mel J. EOP/USTR

From: Michael Pascual <Michael.Pascual@gilead.com>
Sent: Friday, December 15, 2017 5:24 PM
To: Ehlers, Karl R. EOP/USTR; Turner, Nathaniel S
Cc: Lee, Daniel E. EOP/USTR; Barry Featherman; Courtney Gillespie; Thompson, Dean R
Subject: [EXTERNAL] Request to meet with PMO advisors

Karl,

It was a pleasure meeting you today and thanks for your offer to help facilitate a meeting with the Prime Minister's office. Would you and Nat be able to assist with requesting a meeting anytime January 4-8, 2018? Please let me know if you need anything from me to start that process. I also defer to you which advisor in the PM's office would be most useful to engage – Saiful, Efendi, or someone else.

Many thanks,
Mike

Michael Pascual | Director, Government Affairs, Asia | **Gilead Sciences Hong Kong** | Room 2603, 26th Floor, Hysan Place | 500 Hennessy Road | Causeway Bay, Hong Kong | Office: +(b) (6) |

Keppel, Mel J. EOP/USTR

From: Gregg Alton <Gregg.Alton@gilead.com>
Sent: Saturday, November 4, 2017 6:59 PM
To: Griffin, Payne P. EOP/USTR
Cc: Kendall, Elizabeth L. EOP/USTR; Ehlers, Karl R. EOP/USTR; Lee, Daniel E. EOP/USTR
Subject: [EXTERNAL] Thank you from Gilead Sciences
Attachments: Thank you letter to G. Payne Griffin USTR 11.3.17.pdf; Attachments Letter to G. Griffin USTR_ 11317.pdf

Mr. Griffin,

Thank you again for taking the time to meet with me and my team last week. Please find a letter regarding our issues in Malaysia, including updates regarding our data exclusivity rejections, attached.

Gregg

Gregg Alton
Executive Vice President, Corporate and Medical Affairs
Gilead Sciences, Inc.
333 Lakeside Drive, Foster City, CA 94404
(b) (6) (phone)
(b) (6) (private fax)
galton@gilead.com

Keppel, Mel J. EOP/USTR

From: Ehlers, Karl R. EOP/USTR
Sent: Friday, March 23, 2018 3:26 PM
To: Keppel, Mel J. EOP/USTR
Subject: FW: [EXTERNAL] Minister of Domestic Trade

From: Ehlers, Karl R. EOP/USTR
Sent: Saturday, December 9, 2017 10:50 AM
To: Barry Featherman <Barry.Featherman@gilead.com>
Cc: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Subject: Re: [EXTERNAL] Minister of Domestic Trade

Barry
That is great news, thanks for letting us know. Are you also going to see Nat Turner of the Embassy, and Catherine Spillman of FCS? Assuming you will, but just checking as they have their meeting coming up with the Prime Minister's office and I am sure a conversation w you would be helpful to them beforehand. K.

Sent from my iPhone

On Dec 9, 2017, at 9:26 AM, Barry Featherman <Barry.Featherman@gilead.com> wrote:

> Hi Karl and Daniel: Just a note that I am once again enroute to Kuala Lumpur. The Minister of Domestic Trade has sent us a note offering to meet with us on Monday. I'll let you know how the meeting goes. Best, Barry
> Sent from my iPhone

Keppel, Mel J. EOP/USTR

From: Ehlers, Karl R. EOP/USTR
Sent: Friday, March 23, 2018 3:27 PM
To: Keppel, Mel J. EOP/USTR
Subject: FW: Any updates on your requested meeting with Ministry of Health?

-----Original Message-----
From: Ehlers, Karl R. EOP/USTR
Sent: Tuesday, September 19, 2017 3:34 PM
To: Barry Featherman <Barry.Featherman@gilead.com>
Subject: Any updates on your requested meeting with Ministry of Health?

I was just speaking with the Malaysia Embassy, and they were wondering too. Best, Karl

Karl Ehlers
Deputy Assistant U.S. Trade Representative, Southeast Asia
Winder Building
600 17th Street NW
Washington DC 20505
(202) 395-3973 (direct)
(202) 395-6813
(202) (b) (6) (cell)

Keppel, Mel J. EOP/USTR

From: Ehlers, Karl R. EOP/USTR
Sent: Friday, March 23, 2018 3:29 PM
To: Keppel, Mel J. EOP/USTR
Subject: FW: Good Morning

-----Original Message-----
From: Ehlers, Karl R. EOP/USTR
Sent: Tuesday, September 5, 2017 5:36 AM
To: Barry Featherman <Barry.Featherman@gilead.com>; Weisel, Barbara EOP/USTR <Barbara_Weisel@USTR.EOP.GOV>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Subject: RE: Good Morning

Barry,
We were wondering if you have heard back from MYS regarding the meeting requests with Minister of Health or Minister of Trade?
Best, Karl

-----Original Message-----
From: Barry Featherman [mailto:Barry.Featherman@gilead.com]
Sent: Tuesday, August 22, 2017 10:09 AM
To: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Weisel, Barbara EOP/USTR <Barbara_Weisel@ustr.eop.gov>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Subject: Good Morning

Good Morning Karl, Barbara and Daniel: I wanted to check if you possibly have a few minutes to speak today. Many thanks, Best, Barry Featherman

Sent from my iPhone

Keppel, Mel J. EOP/USTR

From: Ehlers, Karl R. EOP/USTR
Sent: Friday, March 23, 2018 3:27 PM
To: Keppel, Mel J. EOP/USTR
Subject: FW: Malaysia

-----Original Message-----
From: Ehlers, Karl R. EOP/USTR
Sent: Thursday, September 14, 2017 12:51 PM
To: Barry Featherman <Barry.Featherman@gilead.com>
Cc: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>; Weisel, Barbara EOP/USTR <Barbara_Weisel@USTR.EOP.GOV>
Subject: RE: Malaysia

Barry,
We hadn't heard about this. As your team gathers information and confirms the current status, please keep us posted.
Best, Karl

-----Original Message-----
From: Barry Featherman [mailto:Barry.Featherman@gilead.com]
Sent: Thursday, September 14, 2017 12:30 PM
To: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Subject: [EXTERNAL] Fwd: Malaysia

Dear Karl: I hope all is well. I send you warm greetings from Singapore. We're very concerned by a report in Malaysia's The Star (the first article below) that Malaysia's cabinet approved issuing compulsory licenses to import generic versions of sofosbuvir to treat patients in public health facilities. Whilst we were aware of this, the concerning part is that Malaysia's Health Ministry said that it is preparing a statement on the development. Additional coverage from Malay Mail Online is included, along with a statement from the Malaysian AIDS Council that notes the government decision was made August 4. I am curious if you have heard any news about the government's forthcoming statement on this development. Many thanks! Barry

***
Government Allows Cheaper Versions Of Hep-C Drug Imports
September 14, 2017
The Star (Malaysia) (Gilead and sofosbuvir mentions)

By Loh Foon Fong

PETALING JAYA: The Cabinet has given approval for Malaysia to issue government-use licences to enable the import of generic versions of the Hepatitis C drug Sofosbuvir.

Confirming this, the Domestic Trade, Cooperatives and Consumerism Ministry said some 400,000 Hepatitis C patients in the country will be able to benefit from cheaper drugs for use in public hospitals.

According to information from the ministry, the Health Ministry tabled a Cabinet paper on the implementation of government rights under Section 84 of the Patents Act last month and that it had agreed to it.

"The Health Ministry got approval from the Cabinet on the execution of these rights," it said in response to questions from The Star.

The Patents Act comes under the purview of the Intellectual Property Corporation of Malaysia – known as MyIPO – under the ministry.

The government-use licence is only for drugs to be used in public health facilities.

Clinical trials are being conducted in cooperation with the Neglected Disease Institute (sic) and an Egyptian generic company in a project to make available generic versions of Sofosbuvir, combined with another drug.

Since Sofosbuvir is patented, a government-use licence is needed to waive the monopoly right and ebale the sale of generic drugs, acting as a key to affordable treatment.

Spread through blood and semen, the disease is caused by a virus that infects the liver, with many patients not even aware of having it until they discover liver damage.

In July, The Star had carried a front-page report that about 400,000 Malaysians were suffering from Hepatitis C but only a fraction could afford the medication, which might cost up to RM300,000 for the full course of treatment.

Malaysia is not given special pricing for drugs by pharmaceutical companies because it its considered a middle-income country.

It was reported that Gilead Science, an American research-based bio-pharmaceutical company, had announced its decision on Aug 24 to expand its HIV and Hepatitis C generic licensing agreement to Malaysia, Thailand, Ukraine and Belarus.

Local think tank Galen Centre for Health and Social Policy chief executive officer Azrul Mohd Khalib said the granting of a Sofosbuvir voluntary licence by Gilead Sciences meant that it would be possible for lower cost generic versions of the life-saving drug to be made available in Malaysia.

Positive Malaysian Treatment Access and Advocacy Groups director Edward Low said the Cabinet's approval of the government-use licence was a good move.

"It is a milestone in making Hepatitis C treatment accessible to Malaysians," he said.

Low also said that government-use licence was a better choice than voluntary licence as this allowed a broader option of drugs that could be used.

When contacted, the Health Ministry said it would prepare a statement on the issue soon.

***

Report: Cabinet Approves Compulsory Licence For Hepatitis C Generics
September 14, 2017
The Malay Mail Online (Gilead and sofosbuvir mentions)

KUALA LUMPUR, Sept 14 — The Cabinet has approved government-use licences to bring in generics of Hepatitis C medicine Sofosbuvir, a report said, despite the drug manufacturer offering Malaysia a voluntary licence.

A government-use or compulsory licence means cheaper generic medication can be produced without the drug patent holder's consent, whereas voluntary licencing, while allowing for significant price reductions, can set price ranges for the pharmaceutical product, depending on terms of the licence contract.

The Domestic, Trade, Cooperatives and Consumerism Ministry told local daily The Star that the Health Ministry received approval from the Cabinet to "execute these rights".

Last month, the Health Ministry tabled a Cabinet paper on the implementation of government rights under Section 84 of the Patents Act regarding the drug.

However, government-use licence means the drug will only be available in public health facilities. Around 400,000 Hepatitis C patients in the country will reportedly benefit from this move, especially since a full treatment costs around RM300,000.

As it is a middle-income country, Malaysia does not receive special pricing for drugs by pharmaceutical companies.

On August 24, Sofosbuvir manufacturer Gilead Sciences announced its decision to expand its HIV and Hepatitis C generic licencing agreement to Malaysia, Thailand, Ukraine and Belarus.

Currently, clinical trials are being conducted with the cooperation of the Neglected Disease Institute and an Egyptian generic company to manufacture Sofosbuvir's generic version that is combined with another drug.

***

Move Beyond Hepatitis C Generics, Think-Tank Tells Health Ministry
September 14, 2017
The Malay Mail Online (Gilead and sofosbuvir mentions)

KUALA LUMPUR, Sept 14 — A medical think-tank urged the Health Ministry today to take advantage of the voluntary licence offered for a Hepatitis C medicine, in order to increase access and open doors to a low-cost drug in the country.

The Galen Centre for Health and Social Policy said Putrajaya should consider negotiating for the best possible deal with Sofosbuvir manufacturer Gilead Sciences, including technical support, concessions, and additional assistance.

“This hard-won development would see increased access to a treatment which will improve the quality of life for patients and most importantly, save lives,” its chief executive Azrul Mohd Khalib said in a statement.

“It represents a moral victory for the government which has worked hard to enhance access for Malaysians to innovative drugs and treatment to treat emerging health challenges.”

The Star reported today that the Cabinet has approved government-use licences to bring in generics of Sofosbuvir, ensuring that the medicine will be available in public health facilities.

A government-use or compulsory licence means cheaper generic medication can be produced without the drug patent holder’s consent; whereas voluntary licensing, while allowing for significant price reductions, can set price ranges for the pharmaceutical product, depending on terms of the licence contract.

“Implementing a government-use license would be outside that framework. It could represent a pyrrhic approach to a long-term problem with possible consequences and complications,” Azrul said.

He listed them as reduced access to future innovative drugs for other diseases, including non-communicable one, the perception of being unfriendly to innovation and intellectual property rights, becoming a less attractive location for clinical trials, and being on the watch list of certain trading partners.

“It is critical to ensure that treatment is affordable for the government and accessible to the patient. Patients also need to actually be found and treated,” he said.

“With infection to disease progression taking up as long as 20 years, screening and treatment adherence could be just as critical as cost in ensuring a successful outcome in the fight against Hepatitis C. These issues should not be neglected or kept at the wayside.”

With the Health Ministry’s move, around 400,000 Hepatitis C patients in the country will reportedly benefit from this move, especially since a full treatment costs around RM300,000.

As it is a middle-income country, Malaysia does not receive special pricing for drugs by pharmaceutical companies.

***
Malaysian AIDS Council Welcomes Government Move To Issue Compulsory License On Lifesaving Hepatitis C Medicines
September 11, 2017
Malaysian AIDS Council Press Release (sofosbuvir mention)

Malaysian AIDS Council welcomes Government move to issue compulsory license on lifesaving hepatitis C medicines

KUALA LUMPUR, 11 September 2017 – The Malaysian AIDS Council (MAC) commends the Malaysian Government's action to issue a compulsory license on hepatitis C drugs, allowing for import of the highly effective but exorbitantly priced medicines at the lowest possible costs from generic drug companies.

This decision, which according to reports was taken by the Government on 4 August 2017, will significantly reduce the financial burden of the Government to provide cure to the thousands of Malaysians living with hepatitis C, not to mention the human cost of this otherwise curable disease.

HCV, the highly infectious viral causative agent of hepatitis C, is a major global public health concern responsible for 399,000 deaths worldwide each year. It is estimated that 71 million people have chronic hepatitis C infection globally.[1]

Meanwhile in Malaysia, 3,393 new HCV cases were reported last year, and as many as 500,000 people or 2.5 per cent of the general population are estimated to be living with HCV[2]. Many more are likely to be infected, as the disease remains asymptomatic until it has progressed to advanced cirrhosis, liver failure or cancer.

Due to the overlapping modes of transmission via the drug injecting route, HCV-HIV co-infections are common among people who inject drugs. HCV prevalence among people who inject drugs in Malaysia is estimated to be between 50 to 67 per cent.[3]

HCV can also be transmitted sexually and can be passed vertically from an infected mother to her baby. However, these modes of transmission are far less common.

Until recently, hepatitis C treatment was based on pegylated interferon and ribavirin therapy, which required weekly injections for 24 to 48 weeks. The therapy has poor treatment outcomes and life-threatening side effects.

The advent of oral direct acting antivirals (DAAs) has altered the course of treatment dramatically with cure rates exceeding 90 per cent and shorter treatment duration. In other words, hepatitis C can now be cured with a relatively safe oral regimen.

However, prohibitive prices have restricted access and use of DAAs in Malaysia. Very few patients have benefited from this new class of drugs.

Currently, the cost of the full hepatitis C treatment under this regimen per patient comes to RM300,000. The exorbitant prices are due to patent monopolies held by multinational pharmaceutical companies over the DAAs, in particular sofosbuvir, which is the backbone DAA for any HCV treatment regimen.

Needless to say, the monopoly and unsustainable prices have been at the expense of the lives of hundreds of thousands of patients – in the context of HCV-HCV co-infection, people who inject drugs – and it is downright unacceptable.

Compulsory licensing is indeed a step in the right direction in eliminating barriers to hepatitis C treatment. It is protected under Section 84 of the Malaysian Patents Act and is compliant with the rules of the World Trade Organisation, specifically its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Malaysia in the past has issued compulsory licenses, most notably for antiretrovirals to treat HIV infections, leading to the national roll out of the free first-line HIV treatment policy for Malaysians living with HIV in 2006 which has since helped close to 90 per cent of those on HIV treatment achieve viral suppression[4].

Following the landmark decision on HIV medicines, this will be second time that the Malaysian Government has ever issued a compulsory license, underscoring the importance of an equitable healthcare environment in combating oft-neglected diseases due to socioeconomic and structural barriers.

As a proponent of universal access to health for all, the MAC fully supports the Government's bold action, aligned with the World Health Assembly's Global Health Sector Strategy on Viral Hepatitis 2016-2021, which envisions the elimination viral hepatitis as a public health threat by 2030.

Going forward, the MAC together with the Ministry of Health Malaysia will capitalise on the gains that have been made in the AIDS response – especially through the harm reduction programme – as the impetus to drive efforts towards cross-disciplinary partnerships and creating opportunities for integrated HIV-HCV continuum of care.

Through the expansion of community-based HIV testing initiatives under the National Strategic Plan for Ending AIDS 2016 – 2030, measures will be taken to create greater demand for and establish linkages to HCV testing.

The MAC has also recently published At the Edge of a Miracle: The HCV Epidemic in Malaysia, a report that, among other things, makes a case for increased investment in DAAs.

[ENDS]

Malaysian AIDS Council

The Malaysian AIDS Council (MAC) was established in 1992 to serve as an umbrella organisation to support and coordinate the efforts of non-governmental organisations (NGOs) working on HIV and AIDS issues in Malaysia. MAC works in close partnership with government agencies, the private sector and international organisations, to ensure a committed and effective NGO-led response to the HIV epidemic. In addition to providing nationwide coverage of HIV prevention, treatment, care and support services, MAC and its Partner Organisations serve as the common voice for communities most affected by HIV and AIDS in the country. Learn more at >www.mac.org.my<<>http://www.mac.org.my<>.

Contact

Malaysian AIDS Council

Zaki Arzmi | 016.292.2948 | zaki@mac.org.my<mailto:zaki@mac.org.my>

_____

[1] World Heath Organization: >http://www.who.int/mediacentre/factsheets/fs164/en/<

[2] Ministry of Health Malaysia

[3] Aceijas C, Rhodes T. Global estimates of prevalence of HCV infection among injecting drug users. International Journal of Drug Policy 2007; 18: 352-358. Hser Y-I, Liang D, Lan Y-C, BK Vicknasingam, Chakrabarti A. Drug abuse, HIV, and HCV in Asian countries. J Neuroimmune Pharmacol 2016. DOI 10.1007/ s11481-016-9665-x

[4] The Joint United Nations Program on HIV/AIDS (UNAIDS) Ending AIDS: Progress towards 90-90-90 Targets: >http://www.unaids.org/sites/default/files/media_asset/Global_AIDS_update_2017_en.pdf<

Keppel, Mel J. EOP/USTR

Subject: FW: Meeting between Minister Mustapa and Ambassador Lighthizer

On Sep 9, 2017, at 5:55 AM, Mohd Firdaus Mohd Ali (b) (6) .gov.my> wrote:

Dear Karl,

I refer to the meeting between Minister Mustapa and Ambassador Lighthizer on 11 September 2017 from 3.30-4.15 pm.

2. We would like to proposed the attached agenda for consideration. Note that this is only to guide the meeting and we do not see any need to specifically go over item 3 of the agenda. In essence, both Minister Mustapa and Ambassador Lighthizer can have a free flow exchange of views. We are cognizant of the fact that the meeting is just around the corner, but please feel free to comment on the agenda if needed. At the very least, it will be used on our part to assist Minister Mustapa in his deliberations.

3. On the list of participants, there would be 10 individuals from our side. The list is attached. It has listed all details should there need be any security clearance required. Please let us know if we need to cut down our representation. On the same note, we would be happy if you could furnish us on the delegation list from your side as well.

4. On logistics, may I seek clarity on the exact location of the meeting. I would assume that you would be the focal point, but please let me know if there is someone I should inform upon our arrival (his/her cellphone number would be the best). On our side, I will be on point.

5. I do apologize on my tardiness in sending this message.

Thank you.

MOHD FIRDAUS MOHD ALI
Second Secretary (Economics)
Embassy of Malaysia
3516, International Court, NW,
Washington, D.C. 20008
UNITED STATES OF AMERICA
TEL: +1-202-572-9739 | CELL: +1-202-431-9381
EMAIL: (b) (6) gov.my

8 September 2017

<image005.png>

From: Bacak, Abigail R. EOP/USTR [mailto:Abigail.R.Bacak@ustr.eop.gov]
Sent: Friday, September 01, 2017 10:52 AM
To: Mohd Firdaus Mohd Ali; Ehlers, Karl R. EOP/USTR
Cc: Weisel, Barbara EOP/USTR; Hairil Yahri Yaacob
Subject: RE: Letter from Minister Mustapa to Ambassador Lighthizer - Request for Meeting

Firdaus—

I have the meeting allotted for 45 minutes but if it goes over we can accommodate.

Please send us a list of attendees when you have a chance.

We look forward to see you all on the 11th.

Thank you,
Abby

From: Mohd Firdaus Mohd Ali [mailto:(b) (6) i.gov.my]
Sent: Friday, September 1, 2017 10:47 AM
To: Bacak, Abigail R. EOP/USTR <Abigail.R.Bacak@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Cc: Weisel, Barbara EOP/USTR <Barbara_Weisel@ustr.eop.gov>; Hairil Yahri Yaacob (b) (6) .gov.my>
Subject: RE: Letter from Minister Mustapa to Ambassador Lighthizer - Request for Meeting

Dear Abigail,

3.30 pm on 11 September 2017 (Monday) would be ideal. On our part, we are locking it in as an hour meeting but let us if Ambassador Lighthizer want to spend more time with Minister Mustapa.

Thank you.

MOHD FIRDAUS MOHD ALI
Second Secretary (Economics)
Embassy of Malaysia
3516, International Court, NW,
Washington, D.C. 20008
UNITED STATES OF AMERICA
TEL: +1-202-572-9739 | CELL: +1-202-431-9381
EMAIL: (b) (6) gov.my

1 September 2017

From: Bacak, Abigail R. EOP/USTR [mailto:Abigail.R.Bacak@ustr.eop.gov]
Sent: Thursday, August 31, 2017 3:06 PM

To: Mohd Firdaus Mohd Ali; Ehlers, Karl R. EOP/USTR
Cc: Weisel, Barbara EOP/USTR; Hairil Yahri Yaacob
Subject: RE: Letter from Minister Mustapa to Ambassador Lighthizer - Request for Meeting

Would 3:30 pm on 9/11 work for you all?

From: Mohd Firdaus Mohd Ali [mailto:(b) (6) gov.my]
Sent: Wednesday, August 30, 2017 6:47 PM
To: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Bacak, Abigail R. EOP/USTR <Abigail.R.Bacak@ustr.eop.gov>
Cc: Weisel, Barbara EOP/USTR <Barbara_Weisel@ustr.eop.gov>; Hairil Yahri Yaacob (b) (6) gov.my>
Subject: Letter from Minister Mustapa to Ambassador Lighthizer - Request for Meeting

Hi Karl and Abigail,

We refer to the possibility of Minister Mustapa to meet with Ambassador Lighthizer in September 2017.

2. Meeting Ambassador Lighthizer is a priority for Minister Mustapa and we are hopeful that such a meeting can be held prior to Prime Minister Najib's meeting with President Trump on 12 September 2017. We think a meeting on 11 September 2017 (Monday) would be the best option. We are quite flexible on the timing but noting your e-mail that consideration is being given for the meeting to be held later on the 11th, we see a window between 2.45 – 4.30 pm to do so. We are happy to consider any proposal on the exact timing (foresee that 45 minutes – 1 hour meeting would suffice); venue ; and the settings of the meeting. We also look forward to know the suggested numbers of participants on your side so that we can coordinate to match the number as well. Details of those attending as well as security clearance (if any) would perhaps be discussed soon as well.

3. In terms of formality, we would like to forward to you a copy of the letter from Minister Mustapa to Ambassador Lighthizer, requesting a meeting during his working visit here in September 2017. We hope that having this letter would facilitate consideration of USTR to meet with Minister Mustapa.

4. We look forward to hearing back from you on this request and we are committed to make this meeting a beneficial one for both sides.

Thank you.

MOHD FIRDAUS MOHD ALI
Second Secretary (Economics)
Embassy of Malaysia
3516, International Court, NW,
Washington, D.C. 20008
UNITED STATES OF AMERICA
TEL: +1-202-572-9739 | CELL: +1-202-431-9381
EMAIL: (b) (6) gov.my

30 August 2017

-----Original Message-----
From: Ehlers, Karl R. EOP/USTR [mailto:Karl_R._Ehlers@ustr.eop.gov]
Sent: Monday, August 28, 2017 2:53 PM
To: Hairil Yahri Yaacob; Mohd Firdaus Mohd Ali
Cc: Bacak, Abigail R. EOP/USTR; Weisel, Barbara EOP/USTR
Subject: Scheduling the Meeting with Ambassador Lighthizer

Dear Hairil, Firdaus:
Regarding the Minister's request to meet with Ambassador Lighthizer during Prime Minister Najib's upcoming visit - I want to introduce you virtually to Abigail Bacak, on the Ambassador's staff, to identify a possible date and time for the event. I understand that the Ambassador is looking at a time later on the 11th, later in the day, and Abby is best positioned to work out the timing and logistics.
Let me know if I can provide further information or help in any way.
All the best, Karl

Karl Ehlers
Deputy Assistant U.S. Trade Representative, Southeast Asia Winder Building
600 17th Street NW
Washington DC 20505
(202) 395-3973 (direct)
(202) 395-6813
(202) (b) (6) (cell)

To report this email as SPAM, please attach the original email as an attachment to spam@1govuc.gov.my by holding Ctrl + Alt + F keys concurrently (for Outlook client) or right click on the email and forward as Attachment (for OWA).

<LIST OF MALAYSIAN DELEGATION.xls>

<Proposed Agenda (Malaysia - 8 September 2017).docx>

TENTATIVE AGENDA

**MEETING BETWEEN H.E. MUSTAPA MOHAMED,
MINISTER OF INTERNATIONAL TRADE AND INDUSTRY, MALAYSIA**

AND

**AMBASSADOR ROBERT LIGHTHIZER,
U.S. TRADE REPRESENTATIVE**

DATE : 11 September 2017
TIME : 1530 – 1615 hrs
VENUE : TBC
Office of United States Trade Representative
600, 17th Street NW, Washington D.C. 20006

1. **Welcoming remarks by Ambassador Robert Lighthizer, U.S. Trade Representative**

2. **Opening remarks by H.E. Mustapa Mohamed, Minister of International Trade and Industry of Malaysia**

3. **Exchange of views:**

   (i) **Highlights of U.S. Administration trade and investment approach and policy;**
   (ii) **U.S. approach on free trade agreements;**
   (iii) **U.S. views of ASEAN;**
   (iv) **Malaysia as U.S.' trade and investment partner;**
   (v) **Malaysia – post TPP-12;**
   (vi) **Updates on TPP-11;**
   (vii) **Updates on RCEP negotiations; *and***
   (viii) **Other areas of specific concern.**

4. **Closing remarks**

Keppel, Mel J. EOP/USTR

From: Ehlers, Karl R. EOP/USTR
Sent: Friday, March 23, 2018 3:36 PM
To: Keppel, Mel J. EOP/USTR
Subject: FW: Meeting with Malaysian Embassy

-----Original Message-----
From: Ehlers, Karl R. EOP/USTR
Sent: Friday, June 23, 2017 4:28 PM
To: Barry Featherman <Barry.Featherman@gilead.com>
Cc: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>; Weisel, Barbara EOP/USTR <Barbara_Weisel@ustr.eop.gov>
Subject: Re: Meeting with Malaysian Embassy

Barry - thanks. Keep us posted on further developments. Best, Karl

Sent from my iPhone

> On Jun 23, 2017, at 3:07 PM, Barry Featherman <Barry.Featherman@gilead.com> wrote:
>
> Dear Karl:
>
> Briana Barron and I had a good meeting at the Embassy of Malaysia. Lorie Ann Morgan, our VP for Intellectual Property, joined by teleconference. At the Embassy we met with Hairil Yahri Yaacob, Minister Counselor (Economics) and Mohd Firdaus Mohd Ali, Second Secretary (Economics). Here are the highlights, Briana and Lorie Ann walked them through the Rejection of Data Exclusivity both from a logistics as well as a substantive perspective. In terms of logistics, they said that it indicates that the letter was sent by registered mail. If the Ministry is unable to produce a receipt for the letter then we have a good argument that the letter was never actually sent. They asked for the name of the person who asked us to pick up the letter as that is not the proper procedure for sending a letter of this type. I have forwarded it to the Embassy. They also said that we should obtain an acknowledgement of a receipt of the appeal by the Ministry. They said from a substantive perspective that one of the other issues (and they would need to do a bit more research here) is that even in the absence of data exclusivity, our data should still be protected under TRIPS. They said that they will prepare a package to send to KL. But separately they encouraged us to meet directly with the officials at the Ministry of Health and they asked if either our commercial representatives or our lawyers have been in touch with the Ministry over this issue. Our lawyers have indeed already been in touch with the Ministry of Health over this issue. They will also ask their headquarters to weigh in with the Ministry of Health and they asked me to send them more information about their Minister's meeting with Gregg Alton which took place at Davos in January. I have done so Thank you for your help in arranging the meeting.
>
>
> Best regards,
>
> Barry.
>
> -----Original Message-----
> From: Ehlers, Karl R. EOP/USTR [mailto:Karl_R._Ehlers@ustr.eop.gov]
> Sent: Friday, June 23, 2017 10:30 AM
> To: Barry Featherman; Lee, Daniel E. EOP/USTR
> Subject: RE: Meeting with Malaysian Embassy
>
> Barry - how did it go yesterday? Best, Karl
>

> -----Original Message-----
> From: Ehlers, Karl R. EOP/USTR
> Sent: Monday, June 19, 2017 2:15 PM
> To: 'Barry Featherman' <Barry.Featherman@gilead.com>
> Subject: RE: Meeting with Malaysian Embassy
>
> Barry:
>
> How's 3 pm on Thursday? The meeting would take place at the Embassy of Malaysia:
> Embassy of Malaysia
> 3516 International Court, NW,
> Washington, D.C. 20008
> I can introduce you all by email if this looks workable.
>
> Best, Karl
>
> -----Original Message-----
> From: Barry Featherman [mailto:Barry.Featherman@gilead.com]
> Sent: Monday, June 19, 2017 11:02 AM
> To: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
> Subject: RE: Meeting with Malaysian Embassy
>
> Dear Karl: I wanted to check if anytime after 3 pm on Thursday will work or alternatively anytime on Friday morning? Best, Barry.
>
> -----Original Message-----
> From: Ehlers, Karl R. EOP/USTR [mailto:Karl_R._Ehlers@ustr.eop.gov]
> Sent: Monday, June 19, 2017 6:49 AM
> To: Barry Featherman
> Subject: Re: Meeting with Malaysian Embassy
>
> Barry that's great - look forward to catching up later - best Karl
>
> Sent from my iPhone
>
>> On Jun 18, 2017, at 11:52 AM, Barry Featherman <Barry.Featherman@gilead.com> wrote:
>>
>> Dear Karl:
>>
>> Many thanks for your message and your kind assistance with this. I am checking with my colleague Briana Barron on her schedule and yes if its fine with you I will give you a ring on Monday morning to schedule the meeting. By that time I will know Briana's schedule as well the schedule of Lorie Ann Morgan who we would ideally like to have join via conference call whilst Briana and I are at the Embassy.
>>
>> Best,
>>
>> Barry.
>>
>>
>> Barry Featherman | Senior Director, International Government Affairs | Gilead Sciences, Inc. | 300 New Jersey Avenue, NW | Suite 650 | Washington, DC 20001 USA | Office: +1 202 (b) (6) |
>>
>>
>>
>> -----Original Message-----

>> From: Ehlers, Karl R. EOP/USTR [mailto:Karl_R._Ehlers@ustr.eop.gov]
>> Sent: Sunday, June 18, 2017 7:19 AM
>> To: Barry Featherman
>> Cc: Lee, Daniel E. EOP/USTR; Weisel, Barbara EOP/USTR; Gregg Alton
>> Subject: Meeting with Malaysian Embassy
>>
>> Mr Featherman:
>>
>> Per our discussion with Gregg Alton, we look forward to arranging a meeting for you and Briana Baron with the Malaysian Embassy this week. Please let me know what windows of time you have available for this meeting, and we'll seek to arrange. The Malaysians confirmed again yesterday they want to do it. My number is (202) 395-3973 if it's easier to talk on Monday to schedule rather than via email. Look forward to it.
>>
>> Best Karl
>>
>> Sent from my iPhone
>
>

Keppel, Mel J. EOP/USTR

From: Ehlers, Karl R. EOP/USTR
Sent: Friday, March 23, 2018 3:27 PM
To: Keppel, Mel J. EOP/USTR
Subject: FW: quick chat?

-----Original Message-----
From: Ehlers, Karl R. EOP/USTR
Sent: Monday, September 25, 2017 3:36 PM
To: Barry Featherman <Barry.Featherman@gilead.com>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Nestor, Shannon M. EOP/USTR <Shannon_M_Nestor@ustr.eop.gov>; Marc Knox <Marc.Knox@gilead.com>; Olson, Christina EOP/USTR <Christina_Olson@ustr.eop.gov>
Subject: RE: quick chat?

Barry,
We look forward to seeing you tomorrow at 1 pm with Gregg Alton, and have arranged for Daniel Lee to lead for us by phone. Thanks for your flexibility on that. The meeting will be in Barbara's office, and we'll have someone ready to meet you in the lobby on arrival.
Best, Karl

-----Original Message-----
From: Barry Featherman [mailto:Barry.Featherman@gilead.com]
Sent: Monday, September 25, 2017 11:44 AM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Nestor, Shannon M. EOP/USTR <Shannon_M_Nestor@ustr.eop.gov>; Marc Knox <Marc.Knox@gilead.com>; Olson, Christina EOP/USTR <Christina_Olson@ustr.eop.gov>
Subject: RE: quick chat?

Thank you Daniel: This will work for us. I wanted to check if it will work for the rest of the team. Gregg Alton and I are available to come to USTR. Best, Barry.

-----Original Message-----
From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Sunday, September 24, 2017 5:12 PM
To: Barry Featherman
Cc: Ehlers, Karl R. EOP/USTR; Nestor, Shannon M. EOP/USTR; Marc Knox; Olson, Christina EOP/USTR
Subject: RE: quick chat?

Hi Barry,

As mentioned last week, I will be in Ottawa for NAFTA, but could call in. Would 1:00pm (during the lunch break for the negotiations) work for everyone?

Best,

Daniel

--
Daniel Lee

Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property Office of the U.S. Trade Representative (USTR) daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

-----Original Message-----
From: Barry Featherman [mailto:Barry.Featherman@gilead.com]
Sent: Friday, September 22, 2017 3:21 PM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Nestor, Shannon M. EOP/USTR <Shannon_M_Nestor@ustr.eop.gov>; Marc Knox <Marc.Knox@gilead.com>
Subject: Re: quick chat?

Dear Daniel, Karl and Shannon: It was very nice to chat this week. I wanted to advise that Gregg Alton will only be in Washington on Tuesday September 26. I wanted to check on your availability to meet between 12:30 pm and 2 pm or between 5 pm and 6 pm? Many thanks, Barry

Sent from my iPhone

> On Sep 21, 2017, at 8:47 AM, Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov> wrote:
>
> Barry,
>
> To confirm, we're all able to do the call on our side. Talk to you soon.
>
> Best,
>
> Daniel
>
> --
> Daniel Lee
> Deputy Assistant U.S. Trade Representative for Innovation and
> Intellectual Property Office of the U.S. Trade Representative (USTR)
> daniel_lee@ustr.eop.gov
> (202) 395-9549 tel
> (202) 395-3891 fax
> -----Original Message-----
> From: Barry Featherman [mailto:Barry.Featherman@gilead.com]
> Sent: Wednesday, September 20, 2017 11:31 PM
> To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
> Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Olson,
> Christina EOP/USTR <Christina_Olson@ustr.eop.gov>; Nestor, Shannon M.
> EOP/USTR <Shannon_M_Nestor@ustr.eop.gov>; Frino, Brian W. EOP/USTR
> (Intern) <Brian.W.Frino@ustr.eop.gov>; Marc Knox
> <Marc.Knox@gilead.com>
> Subject: Re: quick chat?
>
> Ok thank you
>
> Sent from my iPhone
>
>> On Sep 21, 2017, at 11:59 AM, Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov> wrote:
>>
>> Here is the dial-in information:

>>
>> Participant Dial-In: +1 (202) (b) (6) Participant Code: (b) (6)
>>
>> Best,
>>
>> Daniel
>>
>> --
>> Daniel Lee
>> Deputy Assistant U.S. Trade Representative for Innovation and
>> Intellectual Property Office of the U.S. Trade Representative (USTR)
>> daniel_lee@ustr.eop.gov
>> (202) 395-9549 tel
>> (202) 395-3891 fax
>>
>>
>> -----Original Message-----
>> From: Lee, Daniel E. EOP/USTR
>> Sent: Wednesday, September 20, 2017 10:51 PM
>> To: 'Barry Featherman' <Barry.Featherman@gilead.com>
>> Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Olson,
>> Christina EOP/USTR <Christina_Olson@ustr.eop.gov>; Nestor, Shannon M.
>> EOP/USTR <Shannon_M_Nestor@ustr.eop.gov>; Frino, Brian W. EOP/USTR
>> (Intern) <Brian.W.Frino@ustr.eop.gov>; Marc Knox
>> <Marc.Knox@gilead.com>
>> Subject: RE: quick chat?
>>
>> Let's aim for that. I can make it, although I'm not sure yet if all my colleagues can. I'll send around a call-in number ahead of the call.
>>
>> Best,
>>
>> Daniel
>>
>> --
>> Daniel Lee
>> Deputy Assistant U.S. Trade Representative for Innovation and
>> Intellectual Property Office of the U.S. Trade Representative (USTR)
>> daniel_lee@ustr.eop.gov
>> (202) 395-9549 tel
>> (202) 395-3891 fax
>> -----Original Message-----
>> From: Barry Featherman [mailto:Barry.Featherman@gilead.com]
>> Sent: Wednesday, September 20, 2017 9:26 PM
>> To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
>> Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Olson,
>> Christina EOP/USTR <Christina_Olson@ustr.eop.gov>; Nestor, Shannon M.
>> EOP/USTR <Shannon_M_Nestor@ustr.eop.gov>; Frino, Brian W. EOP/USTR
>> (Intern) <Brian.W.Frino@ustr.eop.gov>; Marc Knox
>> <Marc.Knox@gilead.com>
>> Subject: Re: quick chat?
>>
>> Yes of course - how about 10 pm (Seoul time) this evening - -9 am in
>> Washington ? Also Gregg Alton will be in Washington next week and
>> we would like to come in for a meeting if that is possible. Best,

>> Barry
>>
>> Sent from my iPhone
>>
>>> On Sep 21, 2017, at 9:16 AM, Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov> wrote:
>>>
>>> Barry,
>>>
>>> Would it be possible to have a quick phone call this evening in Seoul / Thursday morning in DC before you take off? It would be helpful for us to get a quick status update on where things are as we try to get a handle on all the facts.
>>>
>>> Best,
>>>
>>> Daniel
>>>
>>> --
>>> Daniel Lee
>>> Deputy Assistant U.S. Trade Representative for Innovation and
>>> Intellectual Property Office of the U.S. Trade Representative (USTR)
>>> daniel_lee@ustr.eop.gov
>>> (202) 395-9549 tel
>>> (202) 395-3891 fax
>>>
>>>
>>> -----Original Message-----
>>> From: Barry Featherman [mailto:Barry.Featherman@gilead.com]
>>> Sent: Wednesday, September 20, 2017 7:36 PM
>>> To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
>>> Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Olson,
>>> Christina EOP/USTR <Christina_Olson@ustr.eop.gov>; Nestor, Shannon
>>> M. EOP/USTR <Shannon_M_Nestor@ustr.eop.gov>; Frino, Brian W.
>>> EOP/USTR (Intern) <Brian.W.Frino@ustr.eop.gov>
>>> Subject: Re: quick chat?
>>>
>>> Friday Afternoon
>>>
>>> Sent from my iPhone
>>>
>>>> On Sep 21, 2017, at 8:34 AM, Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov> wrote:
>>>>
>>>> Hi Barry,
>>>>
>>>> Do you mean Thursday afternoon or Friday afternoon DC time? Let us know, and we'll figure out a window.
>>>>
>>>> Best,
>>>>
>>>> Daniel
>>>>
>>>> --
>>>> Daniel Lee
>>>> Deputy Assistant U.S. Trade Representative for Innovation and
>>>> Intellectual Property Office of the U.S. Trade Representative
>>>> (USTR) daniel_lee@ustr.eop.gov
>>>> (202) 395-9549 tel
>>>> (202) 395-3891 fax

>>>> -----Original Message-----
>>>> From: Barry Featherman [mailto:Barry.Featherman@gilead.com]
>>>> Sent: Wednesday, September 20, 2017 7:31 PM
>>>> To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
>>>> Cc: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Olson,
>>>> Christina EOP/USTR <Christina_Olson@ustr.eop.gov>; Nestor, Shannon
>>>> M. EOP/USTR <Shannon_M_Nestor@ustr.eop.gov>; Frino, Brian W.
>>>> EOP/USTR (Intern) <Brian.W.Frino@ustr.eop.gov>
>>>> Subject: Re: quick chat?
>>>>
>>>> Dear Daniel: Thank you for your note. I'm scheduled to fly to
>>>> Washington from Seoul tomorrow and I arrive in DC in the late
>>>> morning. Could we schedule something for the early afternoon?
>>>> Best, Barry
>>>>
>>>> Sent from my iPhone
>>>>
>>>>> On Sep 21, 2017, at 5:40 AM, Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov> wrote:
>>>>>
>>>>> Hi Barry,
>>>>>
>>>>> To follow up on your discussion with Karl this morning, would you have a few minutes to chat by phone tomorrow morning DC time?
>>>>>
>>>>> Best,
>>>>>
>>>>> Daniel
>>>>>
>>>>> --
>>>>> Daniel Lee
>>>>> Deputy Assistant U.S. Trade Representative for Innovation and
>>>>> Intellectual Property Office of the U.S. Trade Representative
>>>>> (USTR) daniel_lee@ustr.eop.gov
>>>>> (202) 395-9549 tel
>>>>> (202) 395-3891 fax
>>>>>
>>>>>

Keppel, Mel J. EOP/USTR

From: Thompson, Dean R <ThompsonDR@state.gov>
Sent: Friday, December 15, 2017 6:30 PM
To: Ehlers, Karl R. EOP/USTR; Turner, Nathaniel S; Michael Pascual
Cc: (U) Spillman, Catherine (FCS); Courtney Gillespie; Owen, Rebecca P; Barry Featherman; Lee, Daniel E. EOP/USTR
Subject: RE: Request to meet with PMO advisors

Adding Catherine and Rebecca. Nat out until after holidays.

_____

From: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Date: December 16, 2017 at 6:41:21 AM GMT+8
To: Turner, Nathaniel S <TurnerNS@state.gov>, Michael Pascual <Michael.Pascual@gilead.com>
Cc: Courtney Gillespie <Courtney.Gillespie@gilead.com>, Thompson, Dean R <ThompsonDR@state.gov>, Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>, Barry Featherman <Barry.Featherman@gilead.com>
Subject: RE: Request to meet with PMO advisors

Mike,
It was great to chat – in particular, thanks for letting us know that you have already responded to the Minister of Domestic Trade and made a proposal per his request. Keep us posted on what you hear from his office.
Re: a contact at the PMO's office when you are next in KL, as we discussed, we think it would be a good idea to socialize your proposal if you can get a meeting. We'll confer with Dean and Nat and Catherine; they will be able to advise on the best way to get a request in.
My coordinates are below.
Best, Karl

Karl Ehlers

Winder Building

600 17th Street NW

Washington DC 20505

(202) 395-3973 (direct)

(202) 395-6813

(b) (6) (cell)

From: Michael Pascual [mailto:Michael.Pascual@gilead.com]
Sent: Friday, December 15, 2017 5:24 PM
To: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>; Turner, Nathaniel S <TurnerNS@state.gov>
Cc: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>; Barry Featherman <Barry.Featherman@gilead.com>; Courtney Gillespie <Courtney.Gillespie@gilead.com>; Thompson, Dean R <ThompsonDR@state.gov>
Subject: [EXTERNAL] Request to meet with PMO advisors

Karl,

It was a pleasure meeting you today and thanks for your offer to help facilitate a meeting with the Prime Minister's office. Would you and Nat be able to assist with requesting a meeting anytime January 4-8, 2018? Please let me know if you need anything from me to start that process. I also defer to you which advisor in the PM's office would be most useful to engage – Saiful, Efendi, or someone else.

Many thanks,
Mike

Michael Pascual | Director, Government Affairs, Asia | Gilead Sciences Hong Kong | Room 2603, 26th Floor, Hysan Place | 500 Hennessy Road | Causeway Bay, Hong Kong | Office: +(b) (6) |

Keppel, Mel J. EOP/USTR

From: Monica He <mhe@bio.org>
Sent: Friday, December 15, 2017 12:28 PM
To: Michael Pascual; Lee, Daniel E. EOP/USTR
Subject: RE: [EXTERNAL] Re: Thank you and follow-up, Gilead Sciences

Ditto – see you soon.

Monica He, PhD
BIO || mhe@bio.org
(b) (6)

From: Michael Pascual [mailto:Michael.Pascual@gilead.com]
Sent: Friday, December 15, 2017 10:24 AM
To: Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>
Cc: Monica He <mhe@bio.org>
Subject: RE: [EXTERNAL] Re: Thank you and follow-up, Gilead Sciences

Sounds good. See you then.

From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
Sent: Friday, December 15, 2017 10:23 AM
To: Monica He; Joseph Damond
Cc: Michael Pascual; Courtney Gillespie; Gregg Alton; Kacy Hutchison; Chuck Clapton; Barry Featherman; Young, Stewart B. EOP/USTR; Ehlers, Karl R. EOP/USTR
Subject: RE: [EXTERNAL] Re: Thank you and follow-up, Gilead Sciences

Mike and Monica,

Sounds good. Let's meet at the main USTR building (600 17th St., NW) at 3:00pm. No WAVES information needed.

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative
for Innovation and Intellectual Property
Office of the U.S. Trade Representative (USTR)
daniel_lee@ustr.eop.gov
(202) 395-9549 tel
(202) 395-3891 fax

From: Monica He [mailto:mhe@bio.org]
Sent: Friday, December 15, 2017 10:08 AM
To: Joseph Damond <jdamond@bio.org>
Cc: Michael Pascual <Michael.Pascual@gilead.com>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov>; Courtney Gillespie <Courtney.Gillespie@gilead.com>; Gregg Alton <Gregg.Alton@gilead.com>; Kacy Hutchison <Kacy.Hutchison@gilead.com>; Chuck Clapton <Chuck.Clapton@gilead.com>; Barry Featherman <Barry.Featherman@gilead.com>; Young, Stewart B. EOP/USTR

<Stewart.B.Young@ustr.eop.gov>; Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov>
Subject: Re: [EXTERNAL] Re: Thank you and follow-up, Gilead Sciences

Hi, happy to join the meeting. Will be at Winder right?

Monica

Monica He, PhD
Director, International Affairs
Biotechnology Innovation Organization (BIO)
(b) (6)
mhe@bio.org

On Dec 15, 2017, at 9:58 AM, Joseph Damond <jdamond@bio.org> wrote:

> Mike, I am not available to meet today, but if possible, I'd like to have Monica He on our staff accompany you (if she is available). I am copying her here.
>
> Joseph Damond
> Executive Vice President,
> International Affairs
> Biotechnology Innovation Organization (BIO)
>
> On Dec 15, 2017, at 9:50 AM, Michael Pascual <Michael.Pascual@gilead.com> wrote:
>
> > Daniel,
> >
> > My Gilead colleagues are out of town and defer to Joe on his availability but I'm available to meet today at 3 pm. Are you in the EEOB? I can send you my WAVES info via separate email.
> >
> > Thanks,
> > Mike
> >
> > -----Original Message-----
> > From: Lee, Daniel E. EOP/USTR [mailto:Daniel_Lee@ustr.eop.gov]
> > Sent: Friday, December 15, 2017 8:09 AM
> > To: Michael Pascual
> > Cc: Courtney Gillespie; Gregg Alton; Kacy Hutchison; Chuck Clapton; Barry Featherman; Joseph Damond (jdamond@bio.org); Young, Stewart B. EOP/USTR; Ehlers, Karl R. EOP/USTR
> > Subject: Re: [EXTERNAL] Re: Thank you and follow-up, Gilead Sciences
> >
> > Hi Mike,
> >
> > Would your colleagues and you be able to meet at 3:00pm today?
> >
> > Best,
> >
> > Daniel
> >
> > --
> > Daniel Lee

Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property
Office of the U.S. Trade Representative (USTR) dlee@ustr.eop.gov
(202) 395-9549

On Dec 14, 2017, at 6:40 PM, Michael Pascual <Michael.Pascual@gilead.com> wrote:

Hi Daniel,

I am in DC tomorrow and was in the meeting with the Minister of Domestic Trade this past Monday. I'd be happy to meet with you tomorrow to give you a readout. Just let me know.

Best,
Mike

Michael Pascual | Director, Government Affairs, Asia | Gilead Sciences Hong Kong | Room 2603, 26th Floor, Hysan Place | 500 Hennessy Road | Causeway Bay<x-apple-data-detectors://1>, Hong Kong | Office: +(b) (6) |

On 14 Dec 2017, at 6:01 PM, Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov<mailto:Daniel_Lee@ustr.eop.gov>> wrote:

Hi Courtney,

Sorry for the delayed response. It's been a crazy week.

How does your schedule look for tomorrow? Or, maybe on Monday or Tuesday?

Best,

Daniel

--
Daniel Lee
Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property
Office of the U.S. Trade Representative (USTR)
daniel_lee@ustr.eop.gov<mailto:daniel_lee@ustr.eop.gov>
(202) 395-9549 tel
(202) 395-3891 fax

From: Courtney Gillespie [mailto:Courtney.Gillespie@gilead.com]
Sent: Sunday, December 10, 2017 11:47 PM
To: Ehlers, Karl R. EOP/USTR <Karl_R._Ehlers@ustr.eop.gov<mailto:Karl_R._Ehlers@ustr.eop.gov>>; Lee, Daniel E. EOP/USTR <Daniel_Lee@ustr.eop.gov<mailto:Daniel_Lee@ustr.eop.gov>>
Cc: Gregg Alton <Gregg.Alton@gilead.com<mailto:Gregg.Alton@gilead.com>>; Kacy Hutchison <Kacy.Hutchison@gilead.com<mailto:Kacy.Hutchison@gilead.com>>; Chuck Clapton <Chuck.Clapton@gilead.com<mailto:Chuck.Clapton@gilead.com>>; Barry Featherman <Barry.Featherman@gilead.com<mailto:Barry.Featherman@gilead.com>>; Michael Pascual <Michael.Pascual@gilead.com<mailto:Michael.Pascual@gilead.com>>; Joseph Damond (jdamond@bio.org<mailto:jdamond@bio.org>) <jdamond@bio.org<mailto:jdamond@bio.org>>

Subject: [EXTERNAL] Thank you and follow-up, Gilead Sciences
Importance: High

Karl and Daniel,

Thank you for taking the time to meet with us last week. We appreciated the opportunity to discuss the compulsory license of sofosbuvir in Malaysia with you. Please find an updated summary and timeline of engagement with the Malaysian government attached for your background. Please let us know if you would like additional information in advance of this week's MC11 meeting.

We would welcome the opportunity to provide a readout of our December 11 meeting with the Ministry of Domestic Trade. Perhaps we can plan to reconnect on Friday, December 15 or the week of December 18.

Best,

Courtney

_____

Courtney Gillespie
Associate Director, Policy
Gilead Sciences
333 Lakeside Drive | Foster City, CA 94404
courtney.gillespie@gilead.com<mailto:courtney.gillespie@gilead.com>| (b) (6)

GILEAD
Advancing Therapeutics.
Improving Lives.

November 3, 2017

G. Payne Griffin
Deputy Chief of Staff
Office of the United States Trade Representative
Executive Office of the President
600 17th Street NW
Washington, DC 20508

Dear Mr. Griffin:

Thank you for taking the time to meet last week to discuss our recent issues in Malaysia.

As we discussed, Malaysia's recent issuance of a compulsory license on our hepatitis C medicine, sofosbuvir, represents a potential violation of TRIPS and other international patent protection regimes.

The Malaysian government's action directly harms Gilead's business in Malaysia. We believe the Malaysian government's recent actions – both the unnecessary and inappropriate use of government license and data exclusivity rejections – warrant U.S. government engagement.

Left unchecked, these decisions set a precedent and send a clear message to other countries, particularly in the region, that disrespect for American intellectual property will be tolerated by the U.S. government. We understand others in the biotech and pharmaceutical industry are closely following our issue due to their concern about the potential impact on their interests in Malaysia and other global markets.

Since we met, we have been informed by the Malaysian government that they have rejected our appeals on the rejection of data exclusivity for both our HIV medicine, Genvoya, and our hepatitis C medicine, Harvoni. No explanation was provided in the appeal rejection letter, which is attached.

We would appreciate USTR's support on these matters and hope Ambassador Lighthizer will communicate the U.S. government's concerns to the Government of Malaysia, preferably by sending a letter expressing the U.S. government's disappointment in these developments. We understand there could also be an opportunity to discuss our issues with the Government of Malaysia on the margins of the upcoming APEC Summit in Danang.

Thank you again for your time and consideration.

Best Regards,

Gregg Alton
Executive Vice President
Corporate and Medical Affairs
Gilead Sciences

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA www.gilead.com
phone 650 574 3000 *facsimile* 650 578 9264

CC:
Ambassador Robert Lighthizer, U.S. Trade Representative
Elizabeth Kendall, Acting Assistant U.S. Trade Representative for Innovation and Intellectual Property
Karl Ehlers, Acting Assistant U.S. Trade Representative for Southeast Asia and the Pacific
Daniel Lee, Deputy Assistant U.S. Trade Representative for Innovation and Intellectual Property

Attachments:
Notification of data exclusivity appeal rejection
Summary of compulsory license issue
Summary of data exclusivity rejections
Correspondence to the Prime Minister
Correspondence to the Minister of Health
Correspondence to the Minister of International Trade
Correspondence to the Director General of the Ministry of Health

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA www.gilead.com
phone 650 574 3000 *facsimile* 650 578 9264

MENTERI PERDAGANGAN DALAM NEGERI,
KOPERASI DAN KEPENGGUNAAN

Our Ref : KPDN[MPDN]100/8/20/2017 (11)
Date : 18 September 2017

General Manager
Gilead Pharmasset LLC
(Gilead Sciences)
303A College Road East
Princeton
New Jersey 08540
United States of America

EXERCISE OF GOVERNMENT'S RIGHTS UNDER SECTION 84 PATENTS ACT 1983 [*ACT 291*]

Please take notice that the Government has decided to authorize Pharmaniaga Logistics Sdn. Bhd, Malaysia to exploit the patented invention for Sofosbuvir tablet 400mg (herewith referred to as "Medicine") pursuant to section 84(1)(a) of the Patents Act 1983 [*Act 291*] ("the Act").

2. The period of exploitation shall commence from 15 October 2017 for a period of three (3) years and shall only be used in all Government hospitals and clinics. Concerning the remuneration for the exploitation of the Medicine, it is proposed that the payment shall be made to your company in the form of royalty and it shall be paid by Pharmaniaga Logistics Sdn. Bhd.

3. Please also take notice your company as the patent owner is hereby given a right to be heard within seven (7) days from the date of this letter.

Thank you.

(DATO' SERI HAMZAH ZAINUDIN)

ARAS 13, NO 13, PERSIARAN PERDANA, PRESINT 2
62623 PUTRAJAYA

Telefon : (603) 8882 5500
Faks : (603) 8882 5518

Web : http://www.kpdnkk.gov.my

Pihak Berkuasa Kawalan Dadah
Drug Control Authority
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj. kami : (85)dlm.BPFK/PPP/07/17 Jld 8
Tarikh : 19 OCT 2017

Pengarah
Gilead Sciences Malaysia Sdn. Bhd.
Level 22, Axiata Tower,
9, Jalan Stesen Sentral 5
Kuala Lumpur Sentral,
50470 Kuala Lumpur.

Tuan,

KEPUTUSAN YB MENTERI KESIHATAN TERHADAP RAYUAN PENOLAKAN PERMOHONAN DATA EKSKLUSIVITI OLEH PIHAK BERKUASA KAWALAN DADAH (PBKD)

BIL	NAMA PRODUK	NO. PENDAFTARAN
1.	Genvoya (Elvitegravir 150mg/Cobicistat 150mg/Emtricitabine 200mg/Tenofovir alafenamide10mg) Film-Coated Tablets	MAL17025022ACZ
2.	HARVONI (Ledipasvir 90mg/Sofosbuvir 400mg) Film-coated Tablets	MAL16035013AZ

Adalah saya merujuk kepada perkara di atas.

2. Dukacitanya dimaklumkan bahawa rayuan tuan di atas ditolak oleh Y.B. Menteri Kesihatan Malaysia.

3. Sila ambil maklum bahawa keputusan ini adalah muktamad sepertimana yang telah diperuntukkan di bawah Peraturan 18, Peraturan-Peraturan Kawalan Dadah dan Kosmetik 1984.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

(DATIN DR. FARIDAH ARYANI BINTI MD. YUSOF) RPh.1197
Setiausaha
Pihak Berkuasa Kawalan Dadah
Kementerian Kesihatan Malaysia
ra/nd/ppp/npra/131017

s.k. Ketua Seksyen Ubat Baru, PPP, NPRA, KKM

GILEAD
Advancing Therapeutics.
Improving Lives.

October 7, 2017

The Honourable Dato' Sri Mohd Najib bin Tun Abdul Razak
Prime Minister of Malaysia
Office of the Prime Minister of Malaysia
Main Block, Perdana Putra Building
Federal Government Administrative Centre
62502 PUTRAJAYA
MALAYSIA

Subject: Gilead Sciences' October 2 meeting with the Ministry of Health regarding Section 84 and voluntary licensing

Your Excellency,

Further to my October 2 letter, I write with additional information about our recent discussions with the Ministry of Health regarding access to Gilead's HIV, hepatitis B and hepatitis C medicines.

We appreciated meeting with Minister Subramaniam and his team on October 2. We discussed ways to better address the unmet medical needs of Malaysian citizens and also shared the benefits of a voluntary license over the use of Section 84. The Ministry said it would take the information under consideration, but also indicated they would likely stand by their decision to pursue Section 84 rights on Gilead's hepatitis C medicine sofosbuvir for use in 12 government hospitals and, at the same time, participate in our voluntary licensing program for private pay patients.

In light of the availability of a voluntary license for not only our hepatitis C medicines, but also our HIV and hepatitis B medicines, we would be disappointed if your government decides to exercise its rights pursuant to Section 84(1)(a) of the Patents Act 1983 [Act 291] on sofosbuvir. We believe the use of Section 84 is unnecessary and may become counterproductive in the development of a sustainable ecosystem of voluntary licensing, which could ultimately help Malaysia reach more patients sooner.

With our agreements in place, Gilead could partner with the Ministry of Health to:

1) Work with voluntary licensees to facilitate the supply of licensed product subject to import permission and regulatory approvals required by the Government of Malaysia, allowing the Ministry of Health to begin serving patients promptly.
2) Negotiate the terms of a direct voluntary license with a [local] manufacturer selected by the Government of Malaysia, which would include provision of applicable drug product technology transfer to such manufacturer, enabling rapid production and scale-up of local manufacturing. Permitting access to licensed sources of active pharmaceutical ingredients through such product technology transfer could also provide a way to treat a large number of patients. This would require reaching an agreement with the [local] manufacture on mutually agreeable terms. This active pharmaceutical ingredient could be used in clinical trial settings, including the Drugs for Neglected Diseases Initiative (DNDi) clinical trials in Malaysia on a hepatitis C treatment combining sofosbuvir with Pharco's investigational drug ravidasvir.
3) Enable access to advanced pan-genotypic regimes.
4) Share best practices to support increased HCV testing.
5) Expand treatment access beyond the 12 hospitals currently identified.

We hope you will consider the benefits of a voluntary licensing approach as you endeavor to treat hepatitis C patients in Malaysia. In the meantime, we intend to appeal the Section 84(1)(a) decision and have requested a hearing before the Minister of Domestic Trade as soon as possible. Gilead is concerned with the procedure by which we were informed of the decision, our opportunity for appeal and the reasons for the decision.

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA www.gilead.com
phone 650 574 3000 *facsimile* 650 578 9264

We are committed to making our innovative HIV/AIDS and hepatitis C treatments available to patients in Malaysia. We hope you will consider the benefits of a voluntary licensing approach as you endeavor to treat hepatitis C patients Malaysia.

Sincerely,

Gregg H. Alton
Executive Vice President, Corporate and Medical Affairs
Gilead Sciences

CC:
HE Datuk Seri KV Sathasivam Subramaniam, Minister of Health
HE Dato' Sri Mustapa Mohamed, Minister of International Trade and Industry
Aaron Brinkworth, Senior Director, Access Operations and Emerging Markets, Gilead Sciences
Barry Featherman, Senior Director, International Government Affairs, Gilead Sciences
Stanley Li, General Manager, Hong Kong, Singapore, Malaysia, Gilead Sciences
Michael Pascual, Director, Government Affairs, Asia, Gilead Sciences

Attachments:
Exercise of Government's Rights Under Section 84 Patents Act 1983
October 2 letter from Gregg Alton to Prime Minister Najib

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA www.gilead.com
phone 650 574 3000 *facsimile* 650 578 9264

GILEAD
Advancing Therapeutics.
Improving Lives.

October 2, 2017

The Honourable Dato' Sri Mohd Najib bin Tun Abdul Razak
Prime Minister of Malaysia
Office of the Prime Minister of Malaysia
Main Block, Perdana Putra Building
Federal Government Administrative Centre
62502 PUTRAJAYA
MALAYSIA

Subject: Gilead Sciences voluntary licensing of HIV and hepatitis C medicines to Malaysia

Your Excellency,

I write regarding the recent addition of Malaysia to the list of countries eligible to receive licensed generic versions of Gilead Sciences' HIV and hepatitis C medicines. I would like to take this opportunity to share the full benefits of our voluntary licensing program, and explain the specific ways in which our voluntary licensing program can help expedite and expand access to generic versions of our medicines.

For your background, Gilead Sciences is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need, including HIV/AIDS and viral hepatitis. Many of our medicines, including Sovaldi® (sofosbuvir, 400mg) and Harvoni® (ledipasvir 90mg/sofosbuvir 400mg), have been approved in Malaysia. Sovaldi and Harvoni are used to treat chronic hepatitis C, a blood-borne virus that affects the liver and can lead to cirrhosis and liver cancer. Sofosbuvir-based regimens represent a medical breakthrough for HCV patients, for whom previous treatment options were much less effective and longer duration with burdensome side effects.

Gilead has also been a leader in the development of antiretroviral therapy for HIV/AIDS. Gilead plays a central role in developing single tablet regimens – with one pill once a day, patients can take all of their medication in each dose. Genvoya, a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older, has been approved in Malaysia. TAF, a component of Genvoya, is a novel targeted prodrug of tenofovir that has demonstrated high antiviral efficacy and improvement in renal and bone safety in clinical trials in combination with other antiretroviral agents.

In August 2017, Gilead expanded our voluntary licensing program to include Malaysia, as well as Thailand, Philippines, Ukraine and Belarus, in order to enable the availability of generic versions of our medicines to help meet the unmet needs of patients who are living with hepatitis C, hepatitis B and HIV in these countries. Gilead is committed to enabling broad access to our medicines in order to address unmet health needs, and we therefore regularly review our access approach. We decided to increase the scope of our access program following a number of discussions over time with government officials, non-governmental organizations and community groups regarding the issues these countries have experienced in their efforts to expand access to hepatitis C, hepatitis B and HIV therapies.

Following are some specific terms which we intend to apply to products sold in these countries, which will be subject to the terms and conditions of the applicable license agreement.

Gilead HCV voluntary license:

- **Licensed Territories:** Addition of **Malaysia, Thailand, Ukraine** and **Belarus** – for a total of 105 countries within the HCV voluntary license territory.
- **Licensed Gilead Compounds** – sofosbuvir, ledipasvir, velpatasvir and voxilaprevir.
- **In-country manufacturing:** Gilead HCV licensees will have the right to have licensed finished product and/or other combination products manufactured in each country within the territory for sale in such country via contract manufacturing arrangements or by issuing a sub-license and using licensed API manufactured in India.

- **Royalties:**
  - For **Malaysia, Thailand** and **Ukraine**, higher royalty rates (to be determined) will apply on net sales of licensed finished product and net sales attributable to licensed API in other combination products.
  - For **Belarus** and for all other countries in the licensed territory, royalty rates on net sales of licensed finished product and nets sales attributable to licensed API in other combination products will remain at 7%.
- **Reduction of Royalties**: Following a licensee's receipt of WHO pre-qualification approval for a product, such licensee's royalty rate with respect to such product will be reduced (rate to be determined).

Gilead HIV voluntary license:

- **Licensed Territories** - Addition of **Malaysia, Ukraine, Philippines** and **Belarus** – for a total of 116 countries within the HIV voluntary license territory (note: Thailand has already been included in the HIV voluntary licensed territory from 2006).
- **Licensed Gilead Compounds** - tenofovir alafenamide, elvitegravir, cobicistat, and bictegravir
- **Royalties** - For **Malaysia, Ukraine**, **Philippines** and **Belarus** and for all other countries in the licensed territory**,** royalty rates on net sales of licensed finished product and net sales attributable to licensed API in other combination products will remain at 5%.

Increased access in Malaysia

We are confident that including Malaysia in our direct license agreements, as well as our indirect license for our HIV medicines through the Medicines Patent Pool (MPP), will help you and the Malaysian government reach patients in need of life-saving HIV and hepatitis C treatments. The agreements would enable access to Gilead's portfolio of sofosbuvir-based direct acting antiviral treatments, which offer people living with hepatitis C a short course of therapy to cure their hepatitis C, with the convenience associated with once-daily single-tablet regimens. To date, more than an estimated 1.5 million patients worldwide have been treated with sofosbuvir-based regimens.

Since the U.S. approval of Sovaldi in 2013, Gilead has brought to market 3 single-table regimens. For example, Harvoni offers significant benefit over previously available regimens, cutting treatment times in half for most patients and delivering cure rates of 94-99% in patients with the most common type (genotype 1). Epclusa (sofosbuvir 400mg, velpatasvir 100mg), which is in clinical trials in Malaysia, is the first all-oral, pan-genotypic (U.S. FDA approved for use in patients with genotypes 1, 2, 3, 4, 5 and 6), once-daily single tablet regimen for the treatment of adults with chronic hepatitis C virus infection. Epclusa was also recently approved for use in patients co-infected with HIV. Vosevi™ (sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg) is a third single-tablet regimen that has been approved in the U.S. and Europe for the re-treatment of chronic hepatitis C virus infection in adults with genotype 1, 2, 3, 4, 5 or 6 previously treated with an NS5A inhibitor-containing regimen, or with genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor. Including Malaysia in our voluntary licensing program as described above would enable access to generic versions of all four of these hepatitis C treatments.

In summary, we believe that it is unnecessary and counterproductive for the Government of Malaysia to exercise its rights pursuant to Section 84(1)(a) of the Patents Act 1983 [Act 291], as our direct licensing agreements could help Malaysia reach more patients sooner. We have expressed these sentiments during our conversations in the United States. With our agreements in place, Gilead could partner with the Ministry of Health to:

1) Work with voluntary licensees to facilitate the supply of licensed product subject to import permission and regulatory approvals required by the Government of Malaysia, allowing the Ministry of Health to begin serving patients promptly.
2) Negotiate the terms of a direct voluntary license with a [local] manufacturer selected by the Government of Malaysia, which would include provision of applicable drug product technology transfer to such manufacturer, enabling rapid production and scale-up of local manufacturing. Permitting access to licensed sources of active pharmaceutical ingredients through such product technology transfer could also provide a way to treat a large

number of patients. This would require reaching an agreement with the [local] manufacture on mutually agreeable terms.

3) Enable access to advanced pan-genotypic regimes.
4) Share best practices to support increased HCV testing.
5) Expand treatment access beyond the 12 hospitals currently identified.

We are committed to making our innovative HIV/AIDS and hepatitis C treatments available to patients in Malaysia. My team appreciated discussing the voluntary licensing program with Minister of International Trade and Industry Mustapa in Washington, D.C. on September 10. We look forward to meeting with Minister of Health Subramaniam in Kuala Lumpur on October 2 to discuss these developments.

Sincerely,

Gregg H. Alton
Executive Vice President, Corporate and Medical Affairs
Gilead Sciences

CC:
HE Datuk Seri KV Sathasivam Subramaniam, Minister of Health
HE Dato' Sri Mustapa Mohamed, Minister of International Trade and Industry
Aaron Brinkworth, Senior Director, Access Operations and Emerging Markets, Gilead Sciences
Barry Featherman, Senior Director, International Government Affairs, Gilead Sciences
Stanley Li, General Manager, Hong Kong, Singapore, Malaysia, Gilead Sciences
Michael Pascual, Director, Government Affairs, Asia, Gilead Sciences

Attachments:
August 22 letter from Gregg Alton to Minister of Health Subramaniam
August 24 letter from Gregg Alton to Minister of International Trade and Industry Mustapa
September 27 letter from Gregg Alton to Minister of Health Subramaniam

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October 7, 2017

HE Datuk Seri KV Sathasivam SUBRAMANIAM
Minister of Health
Malaysia Ministry of Health
Level 13 Block E7 Complex E
Government Federal Administration
62590 Putrajaya
Malaysia

Dear Minister Subramaniam,

Thank you for making the time to speak with me and meet my team. I appreciated the productive discussion to better address the unmet medical needs of Malaysian citizens.

I also appreciated the opportunity to share the benefits of our voluntary licensing program for HIV, hepatitis B and hepatitis C with you and your team. In light of the availability of a voluntary license, we would be disappointed if your government decides to exercise its rights pursuant to Section 84(1)(a) of the Patents Act 1983 [Act 291] on our hepatitis C medicine, sofosbuvir. We believe the use of Section 84 is unnecessary and may become counterproductive in the development of a sustainable ecosystem of voluntary licensing, which could ultimately help Malaysia reach more patients sooner.

We hope you will consider the benefits of a voluntary licensing approach as you endeavor to treat hepatitis C patients in Malaysia. In the meantime, we intend to appeal the Section 84(1)(a) decision and have requested a hearing before the Minister of Domestic Trade as soon as possible. Gilead is concerned with the procedure by which we were informed of the decision, our opportunity for appeal, and the reasons for the decision.

At our meeting we presented several new items for your consideration. We are at your disposal at any time should you have questions regarding our voluntary licensing program. I think that we would both agree that the 7-day deadline to respond to your compulsory license decision should not serve to unduly truncate your ability to fully review our proposal. Although we made an official request for an extension via the Malaysian Embassy in Washington, D.C., I hope that you will look favorably upon our request given the fruitful discussions we have started.

As we discussed, a comprehensive voluntary licensing model approach would better serve your public and private patients, show Malaysia's willingness to use public private partnerships to meet the needs of its citizens, and serve as a strong multinational innovator model that other companies will wish to emulate.

I look forward to further discussions as you consider our voluntary licensing proposal and next steps. As a first step to addressing your questions, I am attaching two lists per your request:

1) A list of our current Indian voluntary licensees; and
2) The contact information for our local representatives.

Sincerely,

Gregg H. Alton
Executive Vice President, Corporate and Medical Affairs
Gilead Sciences

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phone 650 574 3000 *facsimile* 650 578 9264

CC:
Dr. Salmah Bahri, Senior Director, Pharmaceutical Services
Dr. Kamaruzaman Saleh, Director, Pharmacy Practice & Development Division
Dr. Ramli Zainal, Director, National Pharmaceutical Regulatory Agency

Attachments:
Indian Voluntary Licensees
Gilead Local Representatives

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India Voluntary Licensees – HCV

1. Aurobindo Pharma Ltd.
2. Biocon Limited
3. Cadila Healthcare Ltd.
4. Cipla Ltd.
5. Hetero Labs Ltd.
6. Laurus Labs Pvt. Ltd.
7. Mylan Laboratories Ltd.
8. Natco Pharma Ltd.
9. SeQuent Scientific Ltd.
10. Strides Shasun Ltd.
11. Sun Pharmaceuticals Industries Ltd

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Gilead Authorized Local Representatives

For all matters, including those pertaining to compulsory licensing and data exclusivity

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October 2, 2017

HE Datuk Seri KV Sathasivam SUBRAMANIAM
Minister of Health
Malaysia Ministry of Health
Level 13 Block E7 Complex E
Government Federal Administration
62590 Putrajaya
Malaysia

Subject: Additional information from Gilead Sciences regarding voluntary licensing of HIV and hepatitis C medicines

Dear Minister Subramaniam,

Further to my August 22 letter, I write to provide additional information regarding the addition of Malaysia to the list of countries eligible to receive licensed generic versions of our HIV and hepatitis C medicines. I feel that we did not communicate the full benefits of our voluntary licensing program sufficiently, and I hope this letter will explain the specific ways in which our voluntary licensing program can help expedite and expand access to generic versions of our medicines.

Gilead expanded our voluntary licensing program to include Malaysia, as well as Thailand, Philippines, Ukraine and Belarus, in order to enable the availability of generic versions of our medicines to help meet the unmet needs of patients who are living with hepatitis C, hepatitis B and HIV in these countries. Gilead is committed to enabling broad access to our medicines in order to address unmet health needs, and we therefore regularly review our access approach. We decided to increase the scope of our access program following a number of discussions over time with government officials, non-governmental organizations and community groups regarding the issues these countries have experienced in their efforts to expand access to hepatitis C, hepatitis B and HIV therapies.

Following are some specific terms which we intend to apply to products sold in these countries, which will be subject to the terms and conditions of the applicable license agreement.

Gilead HCV voluntary license:

- **Licensed Territories:** Addition of **Malaysia, Thailand, Ukraine** and **Belarus** – for a total of 105 countries within the HCV voluntary license territory.
- **Licensed Gilead Compounds** – *sofosbuvir, ledipasvir, velpatasvir and voxilaprevir*.
- **In-country manufacturing:** Gilead HCV licensees will have the right to have licensed finished product and/or other combination products manufactured in each country within the territory for sale in such country via contract manufacturing arrangements or by issuing a sub-license and using licensed API manufactured in India.
- **Royalties:**
  - For **Malaysia, Thailand** and **Ukraine**, higher royalty rates (to be determined) will apply on net sales of licensed finished product and net sales attributable to licensed API in other combination products.
  - For **Belarus** and for all other countries in the licensed territory, royalty rates on net sales of licensed finished product and nets sales attributable to licensed API in other combination products will remain at 7%.

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- **Reduction of Royalties**: Following a licensee's receipt of WHO pre-qualification approval for a product, such licensee's royalty rate with respect to such product will be reduced (rate to be determined).

Gilead HIV voluntary license:

- **Licensed Territories** - Addition of **Malaysia, Ukraine, Philippines** and **Belarus** – for a total of 116 countries within the HIV voluntary license territory (note: Thailand has already been included in the HIV voluntary licensed territory from 2006).
- **Licensed Gilead Compounds** - *tenofovir alafenamide, elvitegravir, cobicistat, and bictegravir*
- **Royalties** - For **Malaysia, Ukraine**, **Philippines** and **Belarus** and for all other countries in the licensed territory**,** royalty rates on net sales of licensed finished product and net sales attributable to licensed API in other combination products will remain at 5%.

Increased access in Malaysia

We are confident that including Malaysia in our direct license agreements, as well as our indirect license for our HIV medicines through the Medicines Patent Pool (MPP), will help you and the Malaysian government reach patients in need of life-saving HIV and hepatitis C treatments. The agreements would enable access to Gilead's portfolio of sofosbuvir-based direct acting antiviral treatments, which offer people living with hepatitis C a short course of therapy to cure their hepatitis C, with the convenience associated with once-daily single-tablet regimens. To date, more than an estimated 1.5 million patients worldwide have been treated with sofosbuvir-based regimens.

Since the approval of Sovaldi (sofosbuvir) in 2013, Gilead has brought to market 3 single-tablet regimens. For example, Harvoni offers significant benefit over previously available regimens, cutting treatment times in half for most patients and delivering cure rates of 94-99% in patients with the most common type (genotype 1). Epclusa (sofosbuvir 400mg, velpatasvir 100mg), which is in clinical trials in Malaysia, is the first all-oral, pan-genotypic (U.S. FDA approved for use in patients with genotypes 1, 2, 3, 4, 5 and 6), once-daily single tablet regimen for the treatment of adults with chronic hepatitis C virus infection. Epclusa was also recently approved for use in patients co-infected with HIV. Vosevi (sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg) is a third single-tablet regimen that has been approved in the U.S. and Europe for the re-treatment of chronic hepatitis C virus infection in adults with genotype 1, 2, 3, 4, 5 or 6 previously treated with an NS5A inhibitor-containing regimen, or with genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor. Including Malaysia in our voluntary licensing program as described above would enable access to generic versions of all four of these hepatitis C treatments.

In summary, we believe that it is unnecessary and counterproductive for the Government of Malaysia to exercise its rights pursuant to Section 84(1)(a) of the Patents Act 1983 [Act 291], as our direct licensing agreements could help Malaysia reach more patients sooner. We have expressed these sentiments during our conversations in the United States. With our agreements in place, Gilead could partner with the Ministry of Health to:

1) Work with voluntary licensees to facilitate the supply of licensed product subject to import permission and regulatory approvals required by the Government of Malaysia, allowing the Ministry of Health to begin serving patients promptly.
2) Negotiate the terms of a direct voluntary license with a [local] manufacturer selected by the Government of Malaysia, which would include provision of applicable drug product technology transfer to such manufacturer, enabling rapid production and scale-up of local manufacturing. Permitting access to licensed sources of active pharmaceutical ingredients through such product technology transfer could also provide a way to treat a large number of patients. This would require reaching an agreement with the [local] manufacture on mutually agreeable terms.
3) Enable access to advanced pan-genotypic regimes.
4) Share best practices to support increased HCV testing.
5) Expand treatment access beyond the 12 hospitals currently identified.

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We are committed to making our innovative HIV/AIDS and hepatitis C treatments available to patients in Malaysia. I regret that I am unable to travel to Kuala Lumpur to meet with you in person on October 2. However, the following members of my team will be there in person and I will join by phone:

- Aaron Brinkworth, Senior Director, Access Operations and Emerging Markets, Gilead Sciences
- Barry Featherman, Senior Director, International Government Affairs, Gilead Sciences
- Stanley Li, General Manager, Hong Kong, Singapore, Malaysia, Gilead Sciences
- Michael Pascual, Director, Government Affairs, Asia, Gilead Sciences

Sincerely,

Gregg H. Alton
Executive Vice President, Corporate and Medical Affairs
Gilead Sciences

CC:
Aaron Brinkworth, Senior Director, Access Operations and Emerging Markets, Gilead Sciences
Barry Featherman, Senior Director, International Government Affairs, Gilead Sciences
Stanley Li, General Manager, Hong Kong, Singapore, Malaysia, Gilead Sciences
Michael Pascual, Director, Government Affairs, Asia, Gilead Sciences

Attachments: August 22 letter from Gregg Alton

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August 22, 2017

HE Datuk Seri KV Sathasivam SUBRAMANIAM
Minister of Health
Malaysia Ministry of Health
Level 13 Block E7 Complex E
Government Federal Administration
62590 Putrajaya
Malaysia

Subject: Request for meeting to discuss HIV and hepatitis C proposal from Gilead Sciences, Inc.

Dear Minister Subramaniam,

I hope this finds you well since we last met at the February 2015 Wilton Park meeting in Singapore, "HIV co-infections with viral hepatitis: implications for screening and treatment in Asia." I am writing to request a meeting with you to discuss how we can work together to address HIV/AIDS and hepatitis C in Malaysia. We are committed to making our innovative HIV/AIDS and hepatitis C treatments available to patients in Malaysia and would like to propose adding Malaysia to the list of countries eligible to receive licensed generic versions of our HIV and hepatitis C medicines. If your schedule permits, I will be in Australia and can travel to Kuala Lumpur to discuss this proposal with you on Friday, September 1 or anytime that is convenient for you.

For your background, Gilead Sciences is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need, including HIV/AIDS and viral hepatitis. Many of our medicines, including Sovaldi® (sofosbuvir, 400mg) and Harvoni® (ledipasvir 90mg/sofosbuvir 400mg), have been approved in Malaysia. Sovaldi and Harvoni are used to treat chronic hepatitis C, a blood-borne virus that affects the liver and can lead to cirrhosis and liver cancer. Sofosbuvir-based regimens represent a medical breakthrough for HCV patients, for whom previous treatment options were much less effective and longer duration with burdensome side effects. For example, Harvoni offers significant benefit over previously available regimens, cutting treatment times in half for most patients and delivering cure rates of 94-99% in patients with the most common type (genotype 1). A third product, Epclusa (sofosbuvir 400mg, velpatasvir 100mg) is in clinical trials in Malaysia.

Gilead has also been a leader in the development of antiretroviral therapy for HIV/AIDS. Gilead plays a central role in developing single tablet regimens – with one pill once a day, patients can take all of their medication in each dose. Genvoya, a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older, has been approved in Malaysia. TAF, a component of Genvoya, is a novel targeted prodrug of tenofovir that has demonstrated high antiviral efficacy and improvement in renal and bone safety in clinical trials in combination with other antiretroviral agents.

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If you are available to meet, Stanley Li, our General Manager responsible for Malaysia, will join me for the meeting. I have attached the term sheet for our generic licensing agreements for your reference. I have also copied our Senior Director for Government Affairs, Barry Featherman.

Thank you for your consideration of this request. I look forward to the opportunity to meet you soon.

Sincerely,

Gregg H. Alton
Executive Vice President, Corporate and Medical Affairs

CC: Barry Featherman, Director, Government Affairs, Gilead Sciences
Stanley Li, General Manager, Hong Kong affiliate

Attachments: Scaling up antiretroviral treatment sustainably
Chronic hepatitis C treatment expansion

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August 24, 2017

HE Dato' Sri Mustapa Mohamed
Minister of International Trade and Industry
Malaysia Ministry of International Trade and Industry
Menara MITI, No. 7,
Jalan Sultan Haji Ahmad Shah,
50480 Kuala Lumpur
Malaysia

Subject: Request for meeting to discuss HIV and hepatitis C partnership with Gilead Sciences, Inc.

Dear Minister Mohamed,

I hope this finds you well since we last met at the World Economic Forum in January. As I mentioned then, Gilead is committed to making our innovative HIV/AIDS and hepatitis C treatments available to patients in Malaysia. I am pleased to share that we are expanding the reach of our HIV and hepatitis C and HIV voluntary licensing program to include Malaysia, as well as Belarus, Thailand and Ukraine. We would appreciate the opportunity to meet with you to discuss this program expansion. Stanley Li, our General Manager responsible for Malaysia, and Aaron Brinkworth, Senior Director of Access Operations and Emerging Markets, will be in Kuala Lumpur the week of September 4 if your schedule permits.

We decided to increase the scope of our voluntary licensing program following a number of discussions with government officials, non-governmental organizations (NGOs) and community groups regarding the issues Malaysia and these three countries have experienced in expanding access to HIV and hepatitis C therapies. We hope that the inclusion of Malaysia in both our direct HIV and hepatitis C licenses, as well as in our indirect license for our HIV medicines through the Medicines Patent Pool (MPP), will help you and your government reach HIV and hepatitis C patients in need of life-saving treatment.

For your background, Gilead Sciences is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need, including HIV/AIDS and viral hepatitis. Many of our medicines, including Sovaldi® (sofosbuvir, 400mg) and Harvoni® (ledipasvir 90mg/sofosbuvir 400mg), have been approved in Malaysia. Sovaldi and Harvoni are used to treat chronic hepatitis C, a blood-borne virus that affects the liver and can lead to cirrhosis and liver cancer. Our regimens represent a medical breakthrough for HCV patients, for whom previous treatment options were much less effective and longer duration with burdensome side effects. Harvoni cuts treatment times in half for most patients, and has cure rates of 94-99% in patients with the most common type. A third product, Epclusa (sofosbuvir 400mg, velpatasvir 100mg) is in clinical trials in Malaysia.

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Gilead has also been a leader in the development of antiretroviral therapy for HIV/AIDS. Gilead plays a central role in developing single tablet regimens – with one pill once a day, patients can take all of their medication in each dose. Genvoya, a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older, is the most recent Gilead single tablet regimen approved in Malaysia. TAF, a component of Genvoya, is a novel targeted prodrug of tenofovir that has demonstrated high antiviral efficacy and improvement in renal and bone safety in clinical trials in combination with other antiretroviral agents.

Gilead has successfully implemented a voluntary generic licensing program since 2006, with the sole objective of expanding access to our medicines where the need is greatest. Today, Gilead has agreements with numerous generic manufacturers – the majority based in India - granting them rights to develop and distribute low-cost generic versions of our HIV and viral hepatitis medicines. Manufacturers within the program are free to set their own prices for the medicines they produce and sell them in an agreed geography. We are pleased to include Malaysia within the licensed geography and have enabled our direct licensees to provide generic versions of our HIV and hepatitis C in the country.

Thank you for your consideration of this request.

Sincerely,

Gregg H. Alton
Executive Vice President, Corporate and Medical Affairs

CC: Barry Featherman, Director, Government Affairs, Gilead Sciences
Stanley Li, General Manager, Hong Kong affiliate
Aaron Brinkworth, Senior Director, Access Operations and Emerging Markets

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October 31, 2017

YBhg. Datuk Dr Noor Hisham bin Abdullah
Director General of Health
Malaysia Ministry of Health
Level 13 Block E7 Complex E
Government Federal Administration
62590 Putrajaya
Malaysia

Dear Dr. Hisham bin Abdullah,

It was a pleasure to speak with you and Minister Subramaniam on October 2. I write to share additional information regarding access to Gilead Science's HIV, hepatitis B and hepatitis C medicines.

For your background, Gilead Sciences is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need, including HIV/AIDS and viral hepatitis.

In August 2017, Gilead Sciences expanded our voluntary licensing program to include Malaysia, as well as Thailand, Philippines, Ukraine and Belarus, in order to enable the availability of generic versions of our medicines to help meet the unmet needs of patients who are living with hepatitis C, hepatitis B and HIV in these countries. Gilead Sciences is committed to enabling broad access to our medicines in order to address unmet health needs, and we therefore regularly review our access approach. We decided to increase the scope of our access program following a number of discussions over time with government officials, non-governmental organizations and community groups regarding the issues these countries have experienced in their efforts to expand access to hepatitis C, hepatitis B and HIV therapies.

We appreciated the opportunity to discuss the full benefits of our voluntary license program with you and Minister Subramaniam. As we discussed, with the appropriate agreements in place, Gilead Sciences could collaborate with the Ministry of Health to:

1) Work with voluntary licensees to facilitate the supply of licensed product, subject to import and regulatory approvals required by the Government of Malaysia, allowing the Ministry of Health to begin serving patients promptly.

2) Negotiate the terms of a direct voluntary license with a local manufacturer selected by the Government of Malaysia, which would include provision of applicable drug product technology transfer to such manufacturer, enabling rapid production and scale-up of local manufacturing of licensed sofosbuvir, ledipasvir, velpatasvir and voxilaprevir containing regimens. Permitting access to licensed sources of active pharmaceutical ingredients through such product technology transfer could also provide a way to treat a large number of patients. This would require reaching an agreement with the local manufacturer of licensed finished product on mutually agreeable terms.

3) Enable supply of finished products manufactured in India under the voluntary licenses or products made locally in Malaysia under the arrangement described in point 2 above for use in local clinical trial settings if required, including the planned Drugs for Neglected Diseases Initiative (DNDi) clinical trials in Malaysia on a hepatitis C treatment. In such case, the issuance of a government use license would not be necessary.

4) Enable access to advanced pan-genotypic regimes.

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5) Share best practices to support increased HCV testing.

6) Expand treatment access beyond the 12 hospitals currently identified.

Given the availability of a voluntary license for not only our hepatitis C medicines, but also our HIV and hepatitis B medicines, we would be disappointed if the Malaysian government decides to exercise its rights pursuant to Section 84(1)(a) of the Patents Act 1983 [Act 291] on sofosbuvir. We believe the use of Section 84 is in violation of local and international laws and treaties, unnecessary and may become counterproductive in the development of a sustainable ecosystem of voluntary licensing, which could ultimately help Malaysia reach more patients sooner.

Gilead Sciences intends to appeal the Section 84(1)(a) decision and have requested a hearing before the Minister of Domestic Trade as soon as possible. Gilead Sciences is concerned with the procedure by which we were informed of the decision, our opportunity for appeal and the reasons for the decision.

I hope the Ministry of Health will consider the benefits of a comprehensive voluntary model licensing approach, as it would better serve your public and private patients, show Malaysia's willingness to use public private partnerships to meet the needs of its citizens, and serve as a strong multinational innovator model that other companies will wish to emulate.

I look forward to further discussions as the Ministry of Health considers our voluntary licensing proposal and next steps. For your benefit, I have attached my previous correspondence with Minister Subramaniam, as well as the materials he requested during our meeting. If you are interested in contacting any of our current Indian voluntary licensees directly, Aaron Brinkworth, our Senior Director for Access Operations and Emerging Markets, can assist. He can be reached at Aaron.Brinkworth@gilead.com or +1 (650) 522-1969.

Sincerely,

Gregg H. Alton
Executive Vice President, Corporate and Medical Affairs
Gilead Sciences

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CC:
HE Datuk Seri KV Sathasivam Subramaniam, Minister of Health
Dr. Salmah Bahri, Senior Director, Pharmaceutical Services
Dr. Kamaruzaman Saleh, Director, Pharmacy Practice & Development Division
Dr. Ramli Zainal, Director, National Pharmaceutical Regulatory Agency
Aaron Brinkworth, Senior Director, Access Operations and Emerging Markets, Gilead Sciences
Barry Featherman, Senior Director, International Government Affairs, Gilead Sciences
Stanley Li, General Manager, Hong Kong, Singapore, Malaysia, Gilead Sciences
Michael Pascual, Director, Government Affairs, Asia, Gilead Sciences

Attachments:
List of our current Indian voluntary licensees
Contact information for our local representatives
October 7 letter from Gregg Alton to HE Datuk Seri KV Sathasivam Subramaniam
October 2 letter from Gregg Alton to HE Datuk Seri KV Sathasivam Subramaniam
August 22 letter from Gregg Alton to HE Datuk Seri KV Sathasivam Subramaniam

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India Voluntary Licensees – HCV

1. Aurobindo Pharma Ltd.
2. Biocon Limited
3. Cadila Healthcare Ltd.
4. Cipla Ltd.*
5. Hetero Labs Ltd.
6. Laurus Labs Pvt. Ltd.
7. Mylan Laboratories Ltd.**
8. Natco Pharma Ltd.
9. SeQuent Scientific Ltd.
10. Strides Shasun Ltd.
11. Sun Pharmaceuticals Industries Ltd

** Cipla Ltd received WHO prequalification approval for sofosbuvir 400mg tablets*
*** Mylan Laboratories Ltd received WHO prequalification approval for sofosbuvir API and for sofosbuvir 400mg tablets*

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