

2013 DRAFTING REQUEST

Senate Amendment (SA-SB498)

Received: 2/11/2014 Received By: mgallagh
Wanted: As time permits Same as LRB: a1814
For: Paul Farrow (608) 266-9174 By/Representing: Scott R.
May Contact: Drafter: mgallagh
Subject: Trade Regulation - other Addl. Drafters:
Extra Copies: MDK

Submit via email: YES
Requester's email: Sen.Farrow@legis.wisconsin.gov
Carbon copy (CC) to: michael.gallagher@legis.wisconsin.gov

Pre Topic:

No specific pre topic given

Topic:

Various exemptions

Instructions:

See attached

Drafting History:

| <u>Vers.</u> | <u>Drafted</u> | <u>Reviewed</u> | <u>Typed</u> | <u>Proofed</u> | <u>Submitted</u> | <u>Jacketed</u> | <u>Required</u> |
|--------------|-----------------------|-------------------|-----------------------|----------------|-----------------------|-----------------------|-----------------|
| /? | mgallagh 2/12/2014 | jdye 2/12/2014 | | _____ | | | |
| /1 | mgallagh 2/13/2014 | jdye 2/13/2014 | jmurphy 2/12/2014 | _____ | lparisi 2/12/2014 | lparisi 2/12/2014 | |
| /2 | mgallagh 2/19/2014 | jdye 2/19/2014 | jfrantze 2/13/2014 | _____ | sbasford 2/13/2014 | sbasford 2/13/2014 | |

| <u>Vers.</u> | <u>Drafted</u> | <u>Reviewed</u> | <u>Typed</u> | <u>Proofed</u> | <u>Submitted</u> | <u>Jacketed</u> | <u>Required</u> |
|--------------|----------------|-----------------|-----------------------|----------------|-----------------------|-----------------------|-----------------|
| /3 | | | rschluet 2/19/2014 | _____ | sbasford 2/19/2014 | sbasford 2/19/2014 | |

FE Sent For:

<END>

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| /1 | mgallagh 2/13/2014 | jdye 2/13/2014 | jmurphy 2/12/2014 | _____ | lparisi 2/12/2014 | lparisi 2/12/2014 | |
| /2 | | 3/2/19 jld | jfrantze 2/13/2014 | _____ | sbasford 2/13/2014 | sbasford 2/13/2014 | |

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Carbon copy (CC) to: michael.gallagher@legis.wisconsin.gov

Pre Topic:

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Topic:

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Instructions:

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| /? | mgallagh 2/12/2014 | jdyer 2/12/2014 | | _____ | | | |
| /1 | | <i>2/13 jld</i> jmurphy 2/12/2014 | | _____ | lparisi 2/12/2014 | lparisi 2/12/2014 | |

FE Sent For: *Jo 2/13*

<END>

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Requester's email: Sen.Farrow@legis.wisconsin.gov
Carbon copy (CC) to: michael.gallagher@legis.wisconsin.gov

Pre Topic:

No specific pre topic given

Topic:

Various exemptions *OK*

Instructions:

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|--------------|----------------|-----------------|--------------|----------------------------|------------------|-----------------|-----------------|
| 1/? | mgallagh | 1 2/12 jld | jd | <i>[Signature]</i> 2/12 | | | |

FE Sent For:

<END>

Gallagher, Michael

From: Gallagher, Michael
Sent: Tuesday, February 11, 2014 12:31 PM
To: Rausch, Scott
Subject: RE: Amendments to LRB 29996/1; Senate Bill 498 and Assembly Bill 656 relating to Patent Trolls

This looks like it should be a simple, not a substitute amendment. If it looks more extensive after I start drafting, I'll double back.

Mike

Mike Gallagher
Attorney
Wisconsin Legislative Reference Bureau
(608) 267-7511

From: Rausch, Scott
Sent: Tuesday, February 11, 2014 12:30 PM
To: Gallagher, Michael
Subject: RE: Amendments to LRB 29996/1; Senate Bill 498 and Assembly Bill 656 relating to Patent Trolls

Yes, if it is easier to do a sub amendment, then we can offer a substitute.

Scott Rausch
Chief of Staff
Office of Senator Paul Farrow
(608) 266-9174
Scott.Rausch@legis.wi.gov

From: Gallagher, Michael
Sent: Tuesday, February 11, 2014 12:27 PM
To: Rausch, Scott
Subject: RE: Amendments to LRB 29996/1; Senate Bill 498 and Assembly Bill 656 relating to Patent Trolls

Okay. It looks like you want one amendment with the three exemptions, not three separate amendments, right?

Mike Gallagher
Attorney
Wisconsin Legislative Reference Bureau
(608) 267-7511

From: Rausch, Scott
Sent: Tuesday, February 11, 2014 12:22 PM
To: Gallagher, Michael
Subject: Amendments to LRB 29996/1; Senate Bill 498 and Assembly Bill 656 relating to Patent Trolls

Michael,

We have a few amendments to the Patent Troll bill. Bear with me, there are a lot of moving parts with this request.

I have amendment requests from pharmaceutical companies, the University of Wisconsin, and Bio-tech companies. I want to ease all of their concerns.

Attached you will find a document relating to the Virginia model legislation on patent trolling. On page two, in the highlighted section, you will see the language that we believe will ease the concerns of pharmaceuticals.

UW would like an exemption as well, and the example of their request is as follows:

This would go into the new section of the draft that lays out exemptions: **(1) The person is an institution of higher education or a technology transfer organization owned or affiliated with an institution of higher education.**

BioForward would also like an exemption for medical devices.

The following may clear up the requests for all three:

“Exemption.—A patent notification sent by the following shall not be subject to the provisions of this Act:

- 1) A person that is an institution of higher education or a technology transfer organization owned or affiliated with an institution of higher education; or
- 2) A person sending the patent notification to a target that has filed an application to the FDA or USDA for approval of a medical device; or
- 3) A person sending the patent notification to a target for a claim for relief arising under 35 U.S.C. § 271(e)(2) or 42 U.S.C. § 262.”

Sub 3 is the same language from Pharma in the attached document.

Sub 1 ensures that WARF and other public entities (like the Medical College of Wisconsin) that are held to greater levels of accountability are exempted as requested.

Sub 2 provides an exemption when the underlying patents are used in medical devices that require approval by the FDA and USDA as requested by BioForward. This language does not exempt a person from attempting to unfairly enforce the underlying patents to the extent they are NOT used in medical devices that require approval from the FDA or USDA. As an example, a patent covering a processor used in a MRI machine would be exempted when it is asserted against another who is trying to use the same processor in an MRI to be approved by the FDA, but it would not be exempted when it is asserted against a print control system, phone, or non-medical device technology, etc.... This makes sense because of the greater level of oversight for those regulated industries like medical devices and pharmaceuticals but still protects those Wisconsin companies that are not subject to those federal requirements.

I hope this information is clear. If you have any questions please let me know. I can run your questions passed interested parties.

Thank you for your attention to these amendment requests.

Scott Rausch

Chief of Staff

Office of Senator Paul Farrow

(608) 266-9174

Scott.Rausch@legis.wi.gov

Gallagher, Michael

From: Rausch, Scott
Sent: Tuesday, February 11, 2014 12:23 PM
To: Gallagher, Michael
Subject: attachement
Attachments: VA HB375 Patent Troll with amendment.pdf

Attachment....

Scott Rausch

Chief of Staff

[Office of Senator Paul Farrow](#)

(608) 266-9174

Scott.Rausch@legis.wi.gov

14104519D

HOUSE BILL NO. 375
FLOOR AMENDMENT IN THE NATURE OF A SUBSTITUTE
 (Proposed by Delegate O'Quinn
 on January 28, 2014)

(Patron Prior to Substitute—Delegate O'Quinn)

A BILL to amend the Code of Virginia by adding in Title 59.1 a chapter numbered 18.1, consisting of sections numbered 59.1-215.1 through 59.1-215.5, relating to bad faith assertions of patent infringement; penalties.

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 59.1 a chapter numbered 18.1, consisting of sections numbered 59.1-215.1 through 59.1-215.5, as follows:

CHAPTER 18.1.

BAD FAITH ASSERTIONS OF PATENT INFRINGEMENT.

§ 59.1-215.1. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Assertion of patent infringement" means (i) sending or delivering a demand letter to a target; (ii) threatening a target with litigation asserting, alleging, or claiming that the target has engaged in patent infringement; (iii) sending or delivering a demand letter to the customers of a target; or (iv) otherwise making claims or allegations, other than those made in litigation against a target, that a target has engaged in patent infringement or that a target should obtain a license to a patent in order to avoid litigation.

"Demand letter" means a letter, email, or other communication asserting, alleging, or claiming that the target has engaged in patent infringement, or that a target should obtain a license to a patent in order to avoid litigation, or any similar assertion.

"Patent infringement" means any conduct that constitutes infringement pursuant to applicable law, including 35 U.S.C. § 271, as amended.

"Target" means a person residing in, conducting substantial business in, or having its principal place of business in the Commonwealth and with respect to whom an assertion of patent infringement is made.

§ 59.1-215.2. Bad faith assertions of patent infringement.

A. A person shall not make, in bad faith, an assertion of patent infringement.

B. The following shall constitute indicia that a person's assertion of patent infringement was made in bad faith:

1. The demand letter does not contain:

a. The number of the patent that is asserted, alleged, or claimed to have been infringed; or

b. The name and address of the patent's owner or owners and assignee or assignees, if any.

2. The person sends a demand letter to a target without first making a reasonable effort under the circumstances to conduct an analysis comparing the claims in the patent to the target's products, services, and technology, or to identify specific areas in which the products, services, or technology are covered by the claims in the patent.

3. The demand letter does not identify specific areas in which the products, services, and technology are covered by the claims in the patent.

4. The person offers to license the patent for an amount that is not based on a reasonable estimation of the value of a license to the patent.

5. The person making an assertion of patent infringement acts in subjective bad faith, or a reasonable actor in the person's position would know or reasonably should know that such assertion is baseless.

6. The assertion of patent infringement is deceptive, or the person threatens legal action that cannot legally be taken or that is not intended to be taken.

7. The person or its subsidiaries or affiliates have previously filed or threatened to file one or more lawsuits based on the same or similar assertion of patent infringement, the person attempted to enforce the assertion of patent infringement in litigation, and a court found the assertion to be objectively baseless or imposed sanctions for the assertion.

8. The patent alleged to be infringed was not in force at the time the allegedly infringing conduct occurred, or the patent claims alleged to be infringed have previously been held to be invalid.

C. The following shall constitute indicia that a person's assertion of patent infringement was not made in bad faith, but the absence of such indicia shall not constitute evidence of bad faith:

1. The person engages in a reasonable effort under the circumstances to establish that the target has infringed the patent and to negotiate an appropriate remedy.

60 2. The person makes a substantial investment in the use of the patent or in the development,
61 production, or sale of a product or item covered by the patent.

62 3. The person has:

63 a. Demonstrated good faith in previous efforts to enforce the patent or a substantially similar patent;
64 or

65 b. Successfully enforced the patent, or a substantially similar patent, through litigation.

66 4. The person is an institution of higher education or a technology transfer office organization
67 owned by or affiliated with an institution of higher education.

68 D. The lists of indicia in this section are non-exclusive, and all indicia need not be present for a
69 finding of bad faith or good faith.

70 **§ 59.1-215.3. Enforcement; remedies; civil investigative demands; assurances of voluntary**
71 **compliance; restraining prohibited acts.**

72 A. Whenever the Attorney General has reasonable cause to believe that any person has engaged in,
73 or is engaging in, or is about to engage in, any violation of this chapter, the Attorney General is
74 empowered to issue a civil investigative demand. The provisions of § 59.1-9.10 shall apply mutatis
75 mutandis to civil investigative demands issued pursuant to this section.

76 B. The Attorney General or any attorney for the Commonwealth may accept an assurance of
77 voluntary compliance with this chapter from any person subject to the provisions of this chapter. Any
78 such assurance shall be in writing and be filed with and be subject on petition to the approval of the
79 appropriate circuit court. Such assurance of voluntary compliance shall not be considered an admission
80 of guilt or a violation for any purpose. Such assurance of voluntary compliance may at any time be
81 reopened by the Attorney General or the attorney for the Commonwealth for additional orders or
82 decrees to enforce the assurance of voluntary compliance. When an assurance is presented to the circuit
83 court for approval, the Attorney General or the attorney for the Commonwealth shall file, in the form of
84 a complaint, the allegations that form the basis for the entry of the assurance. The assurance may
85 provide by its terms for any relief that an appropriate circuit court could grant, including but not
86 limited to arbitration of disputes between a person subject to the provisions of this chapter and any
87 targets, investigative expenses, civil penalties, and costs, provided, however, that nothing in this chapter
88 shall be construed to authorize or require the Commonwealth, the Attorney General, or any attorney for
89 the Commonwealth to participate in arbitration of violations under this section.

90 C. Notwithstanding any other provisions of law to the contrary, the Attorney General or any attorney
91 for the Commonwealth may cause an action to be brought in the appropriate circuit court in the name
92 of the Commonwealth to enjoin any violation of this chapter. The circuit court having jurisdiction may
93 enjoin such violations notwithstanding the existence of an adequate remedy at law. In any action under
94 this section, it shall not be necessary that damages be proved. Unless the Attorney General or the
95 attorney for the Commonwealth determines that a person subject to the provisions of this chapter
96 intends to depart from the Commonwealth or to remove his property from the Commonwealth, or to
97 conceal himself or his property within the Commonwealth, or on a reasonable determination that
98 irreparable harm may occur if immediate action is not taken, the Attorney General or the attorney for
99 the Commonwealth shall, before initiating any legal proceedings as provided in this section, give notice
100 in writing that such proceedings are contemplated and allow such person a reasonable opportunity to
101 show that a violation did not occur or execute an assurance of voluntary compliance as provided in
102 subsection B. The circuit courts are authorized to issue temporary or permanent injunctions to restrain
103 and prevent violations of this chapter. The circuit court also may award to the Commonwealth a civil
104 penalty of not more than \$2,500 for each violation, reasonable expenses incurred in investigating and
105 preparing the case, and attorneys' fees.

106 D. Any person outside the Commonwealth asserting patent infringement to a target shall be deemed
107 to be transacting business within the Commonwealth within the meaning of subdivision A 1 of
108 § 8.01-328.1 and shall thereby be subject to the jurisdiction of the courts of the Commonwealth.

109 E. Nothing in this chapter authorizes the courts of the Commonwealth, the Attorney General, or any
110 attorney for the Commonwealth to exercise jurisdiction over a claim for relief arising under an Act of
111 Congress relating to patents.

112 **§ 59.1-215.4. Exemptions.**

113 A demand letter or assertion of patent infringement that includes a claim for relief arising under 35
114 U.S.C. § 271(e)(2) or 42 U.S.C. § 262 shall not be subject to the provisions of this chapter.

115 **§ 59.1-215.5. Severability.**

116 If any section, subsection, sentence, part, or application of this chapter is adjudged by any court of
117 competent jurisdiction to be invalid, such judgment shall not affect, impair or invalidate any other
118 section, subsection, sentence, part, or application but shall be confined in its operation to the section,
119 subsection, sentence, part, or application directly involved in the controversy in which such judgment
120 shall have been rendered.

Gallagher, Michael

From: Rausch, Scott
Sent: Tuesday, February 11, 2014 3:46 PM
To: Gallagher, Michael
Subject: RE: Amendments to LRB 29996/1; Senate Bill 498 and Assembly Bill 656 relating to Patent Trolls

Go with your wording, I think it works better.

Scott Rausch

Chief of Staff
Office of Senator Paul Farrow
(608) 266-9174
Scott.Rausch@legis.wi.gov

From: Gallagher, Michael
Sent: Tuesday, February 11, 2014 3:44 PM
To: Rausch, Scott
Subject: RE: Amendments to LRB 29996/1; Senate Bill 498 and Assembly Bill 656 relating to Patent Trolls

Rather than saying "owned by or affiliated with" a university, you may want to consider: "owned, controlled, or operated by, or affiliated with," a university. Let me know if you want to go with that. Otherwise, I will stick with the "owned by or affiliated with."

Thanks.

Mike

Mike Gallagher
Attorney
Wisconsin Legislative Reference Bureau
(608) 267-7511

From: Rausch, Scott
Sent: Tuesday, February 11, 2014 12:30 PM
To: Gallagher, Michael
Subject: RE: Amendments to LRB 29996/1; Senate Bill 498 and Assembly Bill 656 relating to Patent Trolls

Yes, if it is easier to do a sub amendment, then we can offer a substitute.

Scott Rausch

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Mike Gallagher

Attorney

Wisconsin Legislative Reference Bureau

(608) 267-7511

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To: Gallagher, Michael

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BioForward would also like an exemption for medical devices.

The following may clear up the requests for all three:

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- 2) A person sending the patent notification to a target that has filed an application to the FDA or USDA for approval of a medical device; or
- 3) A person sending the patent notification to a target for a claim for relief arising under 35 U.S.C. § 271(e)(2) or 42 U.S.C. § 262.”

Sub 3 is the same language from Pharma in the attached document.

Sub 1 ensures that WARF and other public entities (like the Medical College of Wisconsin) that are held to greater levels of accountability are exempted as requested.

Sub 2 provides an exemption when the underlying patents are used in medical devices that require approval by the FDA and USDA as requested by BioForward. This language does not exempt a person from attempting to unfairly enforce the underlying patents to the extent they are NOT used in medical devices that require approval from the FDA or USDA. As an example, a patent covering a processor used in a MRI machine would be exempted when it is asserted against

another who is trying to use the same processor in an MRI to be approved by the FDA, but it would not be exempted when it is asserted against a print control system, phone, or non-medical device technology, etc.... This makes sense because of the greater level of oversight for those regulated industries like medical devices and pharmaceuticals but still protects those Wisconsin companies that are not subject to those federal requirements.

I hope this information is clear. If you have any questions please let me know. I can run your questions passed interested parties.

Thank you for your attention to these amendment requests.

Scott Rausch

Chief of Staff

Office of Senator Paul Farrow

(608) 266-9174

Scott.Rausch@legis.wi.gov

Gallagher, Michael

From: Rausch, Scott
Sent: Wednesday, February 12, 2014 11:00 AM
To: Gallagher, Michael
Subject: FW: SB 498 amendment

Michael,

BioForward has just provided added input on their requests for the Patent Troll Bill. I hope this information provides a little more insight into what will get them to neutral on the bill.

Regards,

Scott Rausch

Chief of Staff
Office of Senator Paul Farrow
(608) 266-9174
Scott.Rausch@legis.wi.gov

From: Jordan K. Lamb [mailto:jkl@dewittross.com]
Sent: Wednesday, February 12, 2014 10:58 AM
To: Henderson, Patrick
Cc: THOMAS MOORE; Rausch, Scott; Pauls, Jason
Subject: RE: SB 498 amendment

Pat, thank you for sending this. I have gone over your suggestions with a number of my board members last night and this morning. My concern is still with number (2) below. Our goal is to have our medical device companies excluded from this law the same way that you have excluded entities like WARF (number (1)) and our drug development companies (number (3)). Simply, the draft needs to exclude medical device companies from having to comply with the law for demand letters related only to patents for our FDA or USDA approved products. I don't think (2) in your draft accomplishes that. Rather, you make the exclusion from this law contingent on whether the "target" has an FDA or USDA approved device. That seems backwards. We are the ones with the FDA/USDA approved devices and related patents. That's what makes us medical device companies.

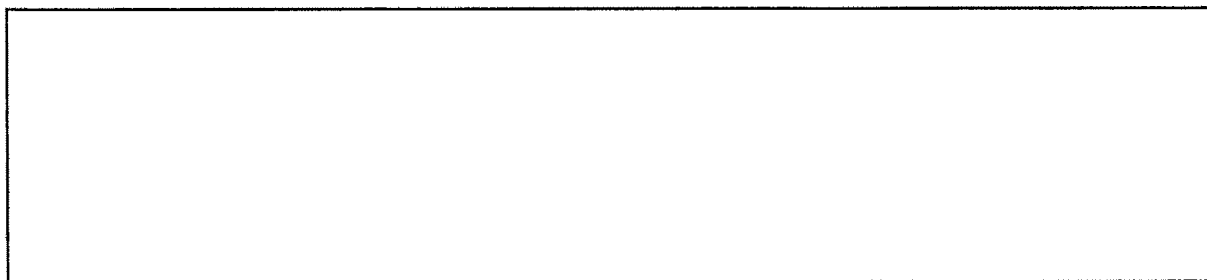
Accordingly, I offer for your consideration a redraft of (2) as follows: (2) A person asserting a claim for relief arising out of a patent on a device, or a component of a device, that is subject to approval by FDA or USDA;

There may be statutory sections that could be cited here like you have cited for the drug development companies, but I need to talk to the medical device counsel in DC for BIO to get those. I don't know them and the patent attorney I was working with last night didn't know them well-enough to offer a list. I will look into that more.

Also, I think the drafting of number (3) is repetitive. You talk about sending the notification in the intro, so it doesn't seem to need to be restated in (3). I suggest this: (3) A person ~~sending the patent notification to a target for~~ asserting a claim for relief arising under 35 U.S.C. § 271(e)(2) or 42 U.S.C. § 262.

I am still discussing this with my affected companies, but I wanted to let you know where we are this morning.

Many thanks,
Jordan



From: Henderson, Patrick [mailto:Patrick.Henderson@qg.com]

Sent: Tuesday, February 11, 2014 11:41 AM

To: Jordan K. Lamb

Cc: THOMAS MOORE; Rausch, Scott; Pauls, Jason

Subject: RE: SB 498 amendment

Hi all,

Here are our thoughts on the exemption. Our general concern is that as proposed it may go too far and exempt trolls who acquire a patent that has applicability in both medical devices and other non-medical industries. They would be able to "hide" behind the medical device applications to troll other industries. Our suggested revisions are below. We think this still accomplishes everyone's goals (Pharma, BioForward, WARF and the WI manufacturing community as a whole).

"Exemption.—A patent notification sent by the following shall not be subject to the provisions of this Act:

- 1) A person that is an institution of higher education or a technology transfer organization owned or affiliated with an institution of higher education; or
- 2) A person sending the patent notification to a target that has filed an application to the FDA or USDA for approval of a medical device; or
- 3) A person sending the patent notification to a target for a claim for relief arising under 35 U.S.C. § 271(e)(2) or 42 U.S.C. § 262."

Sub 3 is the same language for Pharma as proposed by Tom, and should be good to go.

Sub 1 ensures that WARF and other public entities (like the Medical College of Wisconsin) that are held to greater levels of accountability are exempted as requested.

Sub 2 provides an exemption when the underlying patents are used in medical devices that require approval by the FDA and USDA as requested by BioForward. This language does not exempt a person from attempting to unfairly enforce the

underlying patents to the extent they are NOT used in medical devices that require approval from the FDA or USDA. As an example, a patent covering a processor used in a MRI machine would be exempted when it is asserted against another who is trying to use the same processor in an MRI to be approved by the FDA, but it would not be exempted when it is asserted against a print control system, phone, or non-medical device technology, etc.... This makes sense because of the greater level of oversight for those regulated industries like medical devices and pharmaceuticals but still protects those Wisconsin companies that are not subject to those federal requirements.

We hope that everyone could see this as a good compromise that protects everyone's interests without leaving one industry open for abuse by Patent Trolls.

Thanks
Pat

From: Jordan K. Lamb [<mailto:jkl@dewittross.com>]
Sent: Tuesday, February 11, 2014 9:58 AM
To: Henderson, Patrick
Cc: THOMAS MOORE; Rausch, Scott
Subject: RE: SB 498 amendment

Hi Pat. I left you a message on your voicemail a couple of minutes ago. Will try your cell.

The following is what we are coming up with. It is aimed at protecting medical devices and tech transfer. The first red language is aimed at devices, such as those developed by GE, which have underlying IP that can include software. However, all aspects of the device are approved by either FDA or USDA. (I believe that makes them different from other software technology.)

The reference to 35 USC 200-212 in red is the Bayh-Dole Act language. It is aimed at tech transfer from universities and other research institutions.

"Exemption.—A demand letter or assertion of a patent infringement for any intellectual property that requires FDA or USDA approval or that includes a claim for relief arising under 35 U.S.C. § 271(e)(2), 35 U.S.C. § 200-212, or 42 U.S.C. § 262 shall not be subject to the provisions of this Act."

Let me know if you have any questions.
Jordan

From: Henderson, Patrick [<mailto:Patrick.Henderson@qg.com>]
Sent: Tuesday, February 11, 2014 9:34 AM
To: Jordan K. Lamb
Cc: THOMAS MOORE; Rausch, Scott
Subject: RE: SB 498 amendment

Thanks Jordan. I don't want to distract you from that effort but if you get a chance to give me a call that would be much appreciated. I'll be in the office for the next 45 minutes to an hour at 414-566-2345 and then on my cell at 608-575-8472.

Thanks

Pat

From: Jordan K. Lamb [<mailto:jkl@dewittross.com>]
Sent: Tuesday, February 11, 2014 9:25 AM
To: Henderson, Patrick
Cc: THOMAS MOORE; Rausch, Scott
Subject: Re: SB 498 amendment

I am working on language. We probably need to add another USC citation and some narrative. I will get back to you as soon as I can. I am emailing with my board and our patent attorneys.

Sent from Jordan Lamb's iPhone

On Feb 11, 2014, at 9:08 AM, "Henderson, Patrick" <Patrick.Henderson@gg.com> wrote:

How would we accomplish adding medical devises?

From: THOMAS MOORE [<mailto:temoore@tmga.us>]
Sent: Tuesday, February 11, 2014 9:06 AM
To: Rausch, Scott; Henderson, Patrick; Jordan K. Lamb
Subject: SB 498 amendment

Scott / Pat:

I was speaking with Jordan Lamb regarding the amendment to SB 498. While the exception for FDA approved drugs in the VA bill takes care of PhRMA's concerns, it does not speak to FDA approved DEVICES.

We would support adding language that make is clear the exception extends to FDA approved medical devises as well. This would get neutrality from both PhRMA and Bioforward.

Pat, OK by Quad? Scott, OK by your office?

Tom Moore

THOMAS E. MOORE
Thomas E. Moore Government Affairs, Inc.
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Begin forwarded message:

From: THOMAS MOORE <temoore@tmga.us>
Subject: SB 498
Date: February 10, 2014 at 1:33:45 PM CST

To: "Rausch, Scott" <Scott.Rausch@legis.wisconsin.gov>

Cc: "Henderson, Patrick" <patrick.henderson@qq.com>

Scott - I wanted to confirm with you that I spoke with Pat Henderson and Quad Graphics is willing to agree to the amendment contained in this substitute amendment from the state of Virginia.

This provides an exemption for "A demand letter or assertion of patent infringement that includes a claim for relief arising under 35 U.S.C. Section 271(e)(2) or 42 U.S.C. Section 262 shall not be subject to the provision of this chapter."

If this is added to the SB 498, PhRMA will withdraw our objections and I will communicate with PhRMA members and ask for their neutrality on the bill.

Call if you have any questions.

Tom Moore
for PhRMA

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Follow Quad/Graphics in social media

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IN: 2/12 By THURS. 2/13

State of Wisconsin
2013 - 2014 LEGISLATURE

Thales



LRBa17302

MPG:A:...

JLD

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION
SENATE AMENDMENT,
TO SENATE BILL 498

Fixed request sheet

1

1 At the locations indicated, amend the bill as follows:

2

1. Page 3, lines ²¹ and ²³ substitute "subsection (2)" for "this section".

3

2. Page 4, line 4: substitute "subsection (2)" for "this".

4

3. Page 4, line 5: delete "section".

5

4. Page 4, lines ⁶ and ⁸ substitute "subsection (2)" for "this section".

6

5. Page 4, line 15: after that line insert:

7

"(4) EXEMPTIONS. Subsection (2) does not apply to any of the following:

8

(a) A patent notification of an institution of higher education or of a technology transfer organization that is owned, controlled, or operated by, or affiliated with, an institution of higher education.

11

(b) A patent notification based on a target's product, service, process, or

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technology that is the subject of or a part of the target's application to the federal food

attempting to enforce or assert a right in connection with a patent or pending patent on a device, or a component of that device, that is subject to approval by

1 and drug administration[✓] or the federal department of agriculture for approval of a

2 ~~medical device~~

3 (c) A patent notification attempting to enforce or assert a right arising under
4 35 USC 271 (e) (2) or 42 USC 262."[✓]

5 (END)

Gallagher, Michael

From: Rausch, Scott
Sent: Thursday, February 13, 2014 10:30 AM
To: Gallagher, Michael
Subject: RE: SB 498 amendment

Mike,

I have one change to the amendment. In Line 9 on page one, I would like the word affiliated changed to associated.

It is my understanding that such language mirrors federal law.

Thanks for your help.

Scott Rausch

Chief of Staff
Office of Senator Paul Farrow
(608) 266-9174
Scott.Rausch@legis.wi.gov

From: Gallagher, Michael
Sent: Wednesday, February 12, 2014 1:05 PM
To: Rausch, Scott
Subject: RE: SB 498 amendment

Will do.

Mike Gallagher
Attorney
Wisconsin Legislative Reference Bureau
(608) 267-7511

From: Rausch, Scott
Sent: Wednesday, February 12, 2014 12:55 PM
To: Gallagher, Michael
Subject: RE: SB 498 amendment

You may proceed now.

Scott Rausch

Chief of Staff
Office of Senator Paul Farrow
(608) 266-9174
Scott.Rausch@legis.wi.gov

From: Gallagher, Michael
Sent: Wednesday, February 12, 2014 11:33 AM

To: Rausch, Scott
Subject: RE: SB 498 amendment

Do you want me to hold off on putting this through until you get the citations to federal law that Jordan references?

Mike Gallagher
Attorney
Wisconsin Legislative Reference Bureau
(608) 267-7511

From: Rausch, Scott
Sent: Wednesday, February 12, 2014 11:00 AM
To: Gallagher, Michael
Subject: FW: SB 498 amendment

Michael,

BioForward has just provided added input on their requests for the Patent Troll Bill. I hope this information provides a little more insight into what will get them to neutral on the bill.

Regards,

Scott Rausch
Chief of Staff
Office of Senator Paul Farrow
(608) 266-9174
Scott.Rausch@legis.wi.gov

From: Jordan K. Lamb [<mailto:jkl@dewittross.com>]
Sent: Wednesday, February 12, 2014 10:58 AM
To: Henderson, Patrick
Cc: THOMAS MOORE; Rausch, Scott; Pauls, Jason
Subject: RE: SB 498 amendment

Pat, thank you for sending this. I have gone over your suggestions with a number of my board members last night and this morning. My concern is still with number (2) below. Our goal is to have our medical device companies excluded from this law the same way that you have excluded entities like WARF (number (1)) and our drug development companies (number (3)). Simply, the draft needs to exclude medical device companies from having to comply with the law for demand letters related only to patents for our FDA or USDA approved products. I don't think (2) in your draft accomplishes that. Rather, you make the exclusion from this law contingent on whether the "target" has an FDA or USDA approved device. That seems backwards. We are the ones with the FDA/USDA approved devices and related patents. That's what makes us medical device companies.

Accordingly, I offer for your consideration a redraft of (2) as follows: (2) A person asserting a claim for relief arising out of a patent on a device, or a component of a device, that is subject to approval by FDA or USDA;

There may be statutory sections that could be cited here like you have cited for the drug development companies, but I need to talk to the medical device counsel in DC for BIO to get those. I don't know them



2/13 Today Travis

State of Wisconsin
2013 - 2014 LEGISLATURE



LRBa17307
MPG:jld:jm

SENATE AMENDMENT,
TO SENATE BILL 498

9
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1 At the locations indicated, amend the bill as follows:

2 **1.** Page 3, line 21: on lines 21 and 23, substitute “sub. (2)” for “this section”.

3 **2.** Page 4, line 4: substitute “sub. (2)” for “this”.

4 **3.** Page 4, line 5: delete “section”.

5 **4.** Page 4, line 6: on lines 6 and 8, substitute “sub. (2)” for “this section”.

6 **5.** Page 4, line 15: after that line insert:

7 “(4) EXEMPTIONS. Subsection (2) does not apply to any of the following:

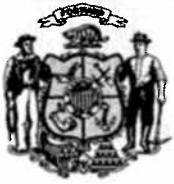
8 (a) A patent notification of an institution of higher education or of a technology
9 transfer organization that is owned, controlled, or operated by, or affiliated with, an
10 institution of higher education. *associated*

11 (b) A patent notification attempting to enforce or assert a right in connection
12 with a patent or pending patent on a device, or a component of that device, that is

1 subject to approval by the federal food and drug administration or the federal
2 department of agriculture.

3 (c) A patent notification attempting to enforce or assert a right arising under
4 35 USC 271 (e) (2) or 42 USC 262.”.

5 (END)



**SENATE AMENDMENT ,
TO SENATE BILL 498**

13

Insert 1-1 ✓

D-Note

1 At the locations indicated, amend the bill as follows:

- 2 **1.** Page 3, line 21: on lines 21 and 23, substitute "sub. (2)" for "this section".
- 3 ~~**2.** Page 4, line 4: substitute "sub. (2)" for "this".~~
- 4 ~~**3.** Page 4, line 5: delete "section".~~
- 5 ~~**4.** Page 4, line 6: on lines 6 and 8, substitute "sub. (2)" for "this section".~~

6 ~~**5.**~~ Page 4, line 15: after that line insert:

7 **"(4) EXEMPTIONS.** Subsection (2) does not apply to any of the following:

8 (a) A patent notification of an institution of higher education or of a technology
9 transfer organization that is owned, controlled, or operated by, or associated with,
10 an institution of higher education.

11 (b) A patent notification attempting to enforce or assert a right in connection
12 with a patent or pending patent on a device, or a component of that device, that is

1 subject to approval by the federal food and drug administration or the federal
2 department of agriculture.

3 (c) A patent notification attempting to enforce or assert a right arising under
4 35 USC 271 (e) (2) or 42 USC 262.”.

5 (END)

d-note
↓



**ASSEMBLY AMENDMENT 2,
TO ASSEMBLY BILL 656**

February 18, 2014 - Offered by Representative NEYLON.

AUTHORS SUBJECT TO CHANGE

This is
Insert 1-1

1 At the locations indicated, amend the bill as follows:

2 **1.** Page 3, line 10: after "subd. 4." insert ", if any,". ✓

3 **2.** Page 3, line 17: delete lines 17 to 19 and substitute:

4 "(c) 1. If a patent notification lacks any of the information required under par.

5 (a), the target may notify the person who made the patent notification that the patent
6 notification is incomplete.

7 2. Within 30 days after the date on which a target notifies a person under subd.

8 1., the person shall provide the target with the information required under par. (a)

9 that is necessary to complete the patent notification." ✓

10 **3.** Page 3, line 21: delete "this section." and substitute "sub. (2) (b) or (c) 2." ✓

11 **4.** Page 3, line 23: delete "this section." and substitute "sub. (2) (b) or to compel

12 a person who has violated sub. (2) (c) 2. with respect to a target to provide the target

13 with the information specified in sub. (2) (c) 2." ✓

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5. Page 4, line 2: after "violation" insert "of sub. (2) (b) or (c) 2". ✓

6. Page 4, line 4: delete "this" and substitute "sub. (2) (b) or (c) 2.". ✓

7. Page 4, line 5: delete that line. ✓

8. Page 4, line 6: delete "this section" and substitute "sub. (2) (b) or (c) 2.". ✓

9. Page 4, line 8: delete "this section." and substitute "sub. (2) (b) or compelling a person who has violated sub. (2) (c) 2. with respect to a target to provide the target with the information specified in sub. (2) (c) 2.". ✓

10. Page 4, line 15: after "notification" insert "that violates sub. (2) (b) or is the subject of a violation of sub. (2) (c) 2.". ✓ (end of ins 1-1)

~~END~~

This IS Insert 1-1 ~~REMOVED~~
Cont

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRBa1730/3dn
MPG:jld:jf

date

Senator Farrow: ✓

This amendment incorporates AA 2 to AB 656.

Please let me know if you have any questions.

Thank you.

Michael Gallagher
Legislative Attorney
Phone: (608) 267-7511
E-mail: michael.gallagher@legis.wisconsin.gov

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRBa1730/3dn
MPG:jld:rs

February 19, 2014

Senator Farrow:

This amendment incorporates AA 2 to AB-656.

Please let me know if you have any questions.

Thank you.

Michael Gallagher
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