Webinar

TRADE SECRETS: IMPLICATIONS FOR PHARMACEUTICAL INNOVATION AND ACCESS

David Levine

24 September 2020

Q&A Session with the Participants

16:03:16
From Global Health Centre Research, Graduate Institute Geneva : Dear all, welcome to the webinar. Please type comments and questions at the chat box. Don't forget to select the option "to: all panelists and attendees" (this is not the default option, you have to manually select it when sending your message).

16:07:55
From Howard Greenfield : Excellent, succinct introduction, Suerie. Thank you!

16:22:11
From Naveen Gopal : Should companies be allowed to conceal certain information with respect to the patented invention ? How to put a check on such a trend ?

16:23:13
From Paul Fehlner : Usually the trade secrets related to patented technology arise after the patent filing, for example the commercial manufacturing process follows long after discovery of the active molecule

16:24:06
From Ekbal Bappukunju : To get a patent all information need be submitted to patent office. Patency is a social contract. For submitting all information the patentee given certain privileges. Is there any trade secrets in relation to drug patency I think not.

16:24:32
From Paul Fehlner : Is there a legal reason why regulatory agencies cannot demand disclosure of trade secrets before approval of a drug? Why not make the regulatory review process public?

16:26:09
From Naveen Gopal : Yes, it must be made public but certain data is protected under Article 39.3 of TRIPS as test data

16:27:15
From Ekbal Bappukunju: Even those data to be made public once the patent period is over. But by /data protection provision this can be delayed that is all

16:28:54
From Marcela Vieira : Can you please explain a bit more how are trade secrets enforced and what are the implications in case of infringement, or involuntary disclosure? Also, if a trade secret is subject to reverse engineering for instance, is it considered an infringement?

16:30:58
From Olena Wagner : The fact that we emphase the pandemic as a good reason to revisit the trade secrecy laws, doesn't it implicitly discount all the other legitimate public health needs that do not constitute a pandemic but still affect people and communities?

16:31:13
From Barbara Milani : In relations to clinical trials, there has been a growing call by public health groups for disclosing information on study design and clinical trials results (positive and negative), did this call resulted in any debate in the change of the trade secret law in the US or in the EU?

16:33:44
From Ellen 't Hoen : Last year's WHA adopted a resolution calling for greater transparency in the pharmaceutical area particularly on pricing. Recently we have been told that the European Commission obliges member states to keep the purchase agreements for COVID-19 vaccines it makes on behalf of MS confidential because they are the 'property of the Commission'. Do you have any comments?

16:34:50
From Janis Lazdins : Can you comment on Trade secrets after IP expiration

16:35:36
From Paul Fehlner : Rather than changing trade secret law, how can we promote sharing of trade secrets in the context of COVID-19 (or other public health needs as @Olena Wagner pointed out)

16:36:59
From Global Health Centre Research, Graduate Institute Geneva : Question sent by Yousuf Vawda:
Some countries, like South Africa, do not have specific legislation dealing with trade secrets, but rely on contractual principles and the 'common law' to protect and enforce trade secrets. Additionally, the SA Constitution places an obligation on a court, in order to give effect to any right in the Bill of Rights, to apply or if necessary develop the common law, and it may develop the rules of that common law to give

effect to those rights. If trade secrets interfere with the ability of citizens to access essential health technologies and thereby impede their right to access health care, as protected in the Constitution, can a case be made for the development of such common law rules as they relate to trade secrets to be developed so as to admit exceptions in pursuit of legitimate public policy objectives? Are you aware of any jurisdiction where such an approach might have been adopted?

16:37:08
From Gabriela Arguedas : Exactly, Olena. I was going to make that question. There is something of a double standard in the IP / Big Pharma world. There are so many tragic public health issues getting worse because of the lack of access to data and IP in drugs, Now is a global issue because so many people in the Global North are suffering. But what would have been under debate, in terms of IP, trade secrets and pharma innovation now if the pandemic wouldn't have hit the Global North so hard?

16:37:39
From Naveen Gopal : Sir, what is the scope of using the public interest exception provided under Article 39.3 of TRIPS during these times of Covid ?

16:38:39
From Faheem Ahmed: How overcome the contextual values, role of non civilian involvement regulation in public health trade secrets ?

16:40:03
From Roz Scourse : Would access to essential information in pharmaceutical licensing and sub-licensing contracts for COVID-vaccines (for example) that is needed to ensure that access/tech transfer etc. is maximised globally come under a public health exception? (including where the R&D for said product was partially or completely subsidized by public money - would this make a difference?)

16:42:41
From rupali mukherjee : How can developing countries navigate trade secrets to access crucial vaccines or drugs during the Covid pandemic? Will WHO C Tap help?

16:43:30
From Gabriela Arguedas : Dr. Levine, what is your opinion about the IP rights pool that WHO and several countries (mostly for the Global South) have proposed as a way to share information, data, etc, to further cooperation in this global crisis?

16:43:46
From Fouad Badaoui : A global committee of experts to go over the data pool of a group of volunteering competitors (that would agree to sharing TS if the committee rules it) seems like a working concept. But how would those companies be incentivized to commit pooling their data and abiding by the committee's decisions? And what authority would that committee have, and who would provide it?

16:45:08
From Vitor Ido : Thank you for the great presentation. Could a trade secret be required to be disclosed/shared under antitrust/competition laws, similarly to FRAND licensing? Would there be a case where under IP law a trade secret could be

deemed legitimate but under competition law a disclosure/sharing requirement would be needed?

16:46:10
From Paul Fehlner : Exceptions and ambiguity provide opportunity for delay, undermining the benefit of transparency, especially in an emergency situation. How can we enable sharing of important clinical and manufacturing information without introducing complex, expensive, and most importantly time-consuming review processes.

16:49:12
From Paul Fehlner : Regarding competition law: under what circumstances is sharing of trade secrets a violation of antitrust/competition law?

16:55:06
From Gabriela Arguedas : Fantastic talk, thank you very much to the organizers and to Dr. Levine.

16:56:25
From Paul Fehlner : I second @Gabriela Arguedas

16:59:03
From rupali mukherjee : Thanks much for the discussion, and for taking up my question.

17:04:58
From Paul Fehlner : Dr. Levine's emphasis on the commercial benefit of transparency is critical to engaging the private sector. Doing well by doing good will more effectively lead to change. Otherwise, conservative tendencies will result in maintaining trade secrets.

17:06:02
From Gabriela Arguedas : Agree with you, Paul.

17:07:26
From Helena Nygren-Krug : Thanks for excellent webinar and discussion!

17:07:42
From rupali mukherjee : would be great if you can share Dr Levine's email

17:08:43
From Global Health Centre Research, Graduate Institute Geneva : You can find Prof. Levine's bio and contact information here:
https://www.elon.edu/u/directory/profile/?user=dlevine3

17:09:43
From Global Health Centre Research, Graduate Institute Geneva : Thank to all for participating in the webinar. Recordings and materials from all webinars of the series are available at the Knowledge Portal on Innovation and Access to Medicines: www.knowledgeportalia.org

17:09:29
From Global Health Centre Research, Graduate Institute Geneva : Save the date for the next webinar on October 29, 4pm-5pm CET, with Julia Barnes-Weise, Executive Director, The Global Health Innovation Alliance Accelerator (GHIAA), presenting the Master Alliance Provisions Guide (MAPGuide). https://ghiaa.org/mapguide-home/

17:09:39
From Vitor Ido : Thank you very much, prof. Levine!

17:09:41
From Gabriela Arguedas : Thank you very much

17:09:57
From rupali mukherjee to All panelists : Thank you

17:10:00
From Ellen 't Hoen to All panelists : Thank you David and Suerie for a great session.

17:10:04
From Faheem Ahmed to All panelists : thanks

17:10:06
From Naveen Gopal to All panelists : Thank you Sir

17:10:07
From Fouad Badaoui : thank you very much!

17:10:17
From Lakshmi Menon to All panelists : thank you very much