

WIPO Symposium on Trade Secrets and Innovation 2022

Topic 7: “Trade Secrets in Action: Development and Dissemination of Medical Technologies”

Current challenges for in Brazil (and Latin America) – A medical device practical perspective

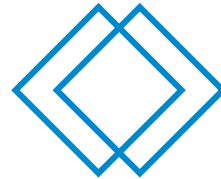
Geneva, May 24, 2022

Benny Spiewak
SPLaw Brazil



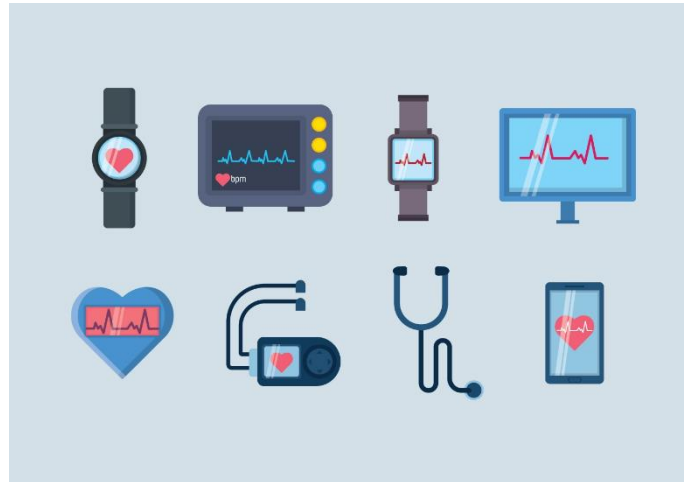
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PRIORITY AREAS - MEDTECH



Information Access Act

Limits for a third party to access confidential information submitted to a regulatory authority while seeking marketing authorization



Used/Refurbished Act

How to balance privileged information and right to repair, maintain and/or refurbish devices?

General Data Protection Act - LGPD

How to balance data processor and data subject rights, e.g., how dataflow works?

Competing Definitions

Different statutes present distinct (and possibly conflicting) definitions to privileged information.

Brazil and Trade Secrets



TRIPS

Information that is secret, that has commercial value because it is secret and that has been subject to reasonable steps to keep it secret



INDUSTRIAL PROPERTY LAW

Confidential knowledge usable in industry, commerce or services, except that which is of public knowledge or which is obvious to a person skilled in the art, to which THEY have had access by means of: (a) contractual or employment relationship, even after the termination of the contract; (b) directly or indirectly by illicit means or to which they has had access by fraud; (c) results of tests or other undisclosed data the elaboration of which involved considerable effort and which has been presented to government entities as a condition for approving the commercialization of products.



INFORMATION ACCESS ACT

This Law does not exclude existing legal protection for confidential information and trade secrets



National Data Protection Agency -

Wearable user "X" requested access to their personal data, as used by company "Y", which has denied access to dataflow and inter-device communication structure-related data



"X"'s next step

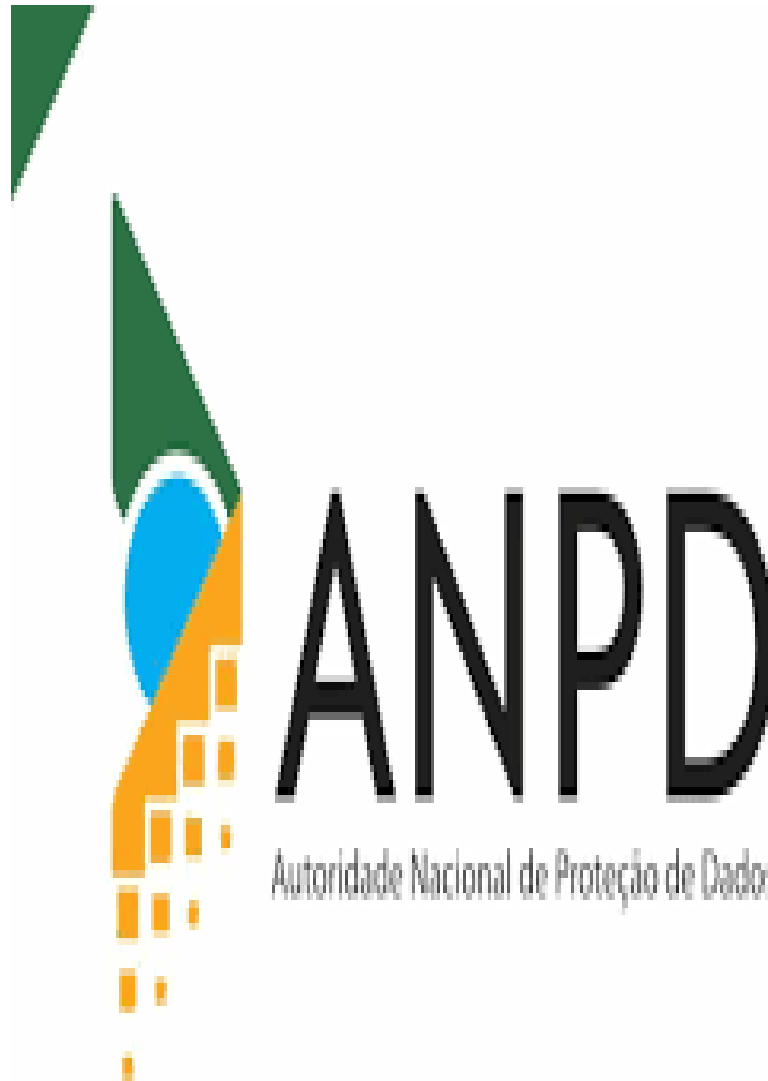
Data subject complained to the ANPD



ANPD

"X" used to be legal counsel to a competitor of "Y".

Does it seem reasonable to withhold such information?



GENERAL DATA



Federal Accountability Office - TCU

“X” filed a FOIA-type request, asking ANVISA to share: (a) copy of the premarket submission data (“redact as you see fit”) filed by “Y”; and (b) *info re. decision making process by ANVISA*



ANVISA (assertive) reaction

Denied (three times) access to both (a) and (b). “By accessing parts of the data, “X” would gain unauthorized and illegal advantage over “Y”; and the Agency follows the Law and associated legal principles, but structure of internal discussions are private



TCU

Sided with ANVISA. “Confidential information is not subject to the Brazilian Freedom of Information Act and such fact is not inconsistent with Brazilian Constitution”





Used and Refurbished Devices Act

Classes I and II devices may be refurbished by non-manufacturers, while only manufacturers full hold blueprints, know how



Liability

Vendors want undisclosed data to provide services



ANVISA

So far, acting as a mediator

Should antitrust authorities decide?

Should there be a limitation of liability?

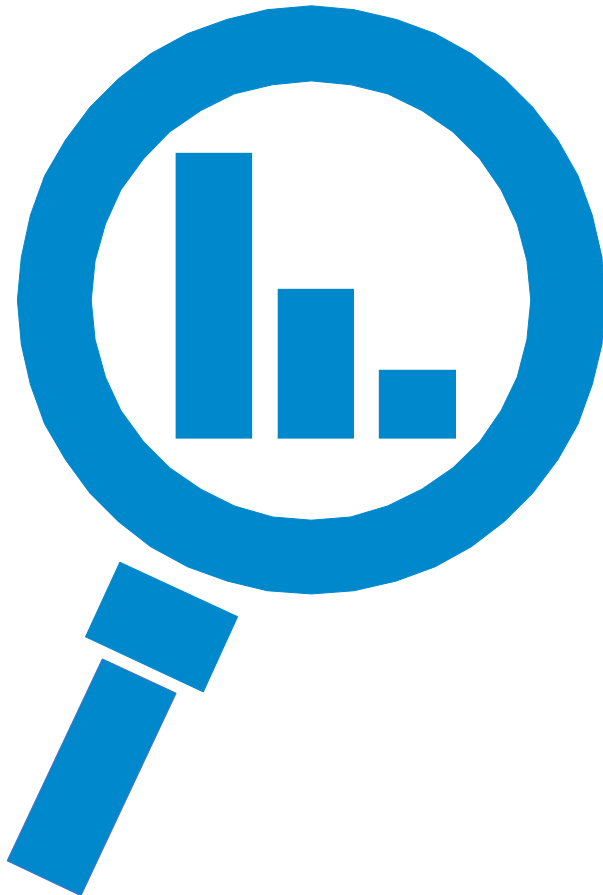
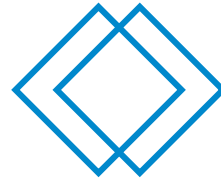
TS less about assembly. More about inputs, vendors and calibration



Agência Nacional de Vigilância Sanitária

GENERAL DATA

What companies can do?



Identify

How extensively is it known by internal colleagues? What measures are taken to protect it? How valuable is it? How hard and expensive would it be for competitors to achieve a similar result without it?



Conceptually challenge

Does the local requirement ask submission? Think local



Monitored filing

Should you highlight the existence of trade secrets?

Instructions as to how the agency needs to handle the info? Redacts.



Train the monitors

Build bridges: R&D, regulatory and legal. NDAs (alone) will not help

Former employees: Did you talk to them?

Merci!

Thank you!

Obrigado!

Benny.Spiewak@splaw.com.br /

<https://www.linkedin.com/in/bennyspiewak/>