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Addressing Open Source Software Issues as Life Science Companies Embrace Hi-Tech Solutions

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The use of open source software ("OSS") in modern technical innovations is increasingly prevalent. For example, incorporation of OSS in innovations within the life sciences has become a relatively common practice as life sciences companies pursue technology-based solutions in the expanding personalized healthcare market. These solutions at the interface of life sciences and hi-technology can range from software-based products to evaluate whether a patient will benefit from a particular therapy to systems that monitor patient compliance with prescribed therapies. OSS can provide companies with quick and cost-effective solutions to many software-related objectives, which can be appealing to those racing to bring products to a competitive market.

Companies considering the use of OSS must, however, be aware of the consequences associated with incorporating OSS into a product's code, particularly with respect to the licenses attached to OSS which often create limitations on associated intellectual property rights. Failure to adequately recognize and address the intellectual property issues raised by the utilization of OSS and their associated licenses can greatly diminish a product's commercial value.

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WHAT IS OSS?

Generally, OSS is computer software that can be "freely accessed, used, changed and shared (in modified or unmodified form) by anyone."[1] Taking advantage of OSS allows software developers to incorporate the work of others to increase efficiency and essentially avoid having to reinvent a previously invented wheel.[2] While OSS is usually available for free, such software is frequently distributed under an OSS license with terms that will limit how a subsequent developer can commercialize a product containing the OSS.

There are many types of OSS licenses with a wide array of terms that may attach to products incorporating OSS. For example, certain OSS licenses prohibit the modification of the OSS work and thus may prohibit the distribution of products containing the OSS in a modified form. OSS licenses can also carry "copy-left" provisions which allow for derivative works but require those derivative works to carry the same OSS license as the original work, essentially prohibiting the sale of products containing the OSS.[3]

Consequently, life sciences companies need to be aware of the presence and type of licenses attached to any OSS incorporated into their products and the ramifications the associated licenses can have on product commercialization.

ISSUES TO CONSIDER

When a life sciences company is faced with a situation where OSS may have been integrated during product development, there are certain things to consider. For example, the company should first confirm the existence of any OSS. While this can be as simple as asking product developers whether OSS was incorporated during software development, often the situation is more complicated. It may be that the software was developed by a third party or even if it was developed in-house it is quite possible that one or more of the developers are no longer associated with the company. In such instances, software composition analysis services can be engaged to review source code, identify, and locate OSS integrated into the product.

Next, life sciences companies that find themselves with OSS in their product should understand what kind of licenses are associated with the incorporated OSS. The specific type of license associated with the OSS can have a significant impact on the future marketability of the product and thus needs to be well understood. Also, situations can arise where a product incorporates multiple OSSs, two or more of which may have licenses with terms that conflict with each other. In such situations, companies need to understand how the conflicting terms will be interpreted and applied.

OSS CONFIRMATION

Finally, once the existence of the OSS is confirmed, a life sciences company should decide how to best address the situation. At this point, there are a lot of factors to consider. For example, the pervasiveness of the OSS within the product's software is consequential. Is the OSS integrated throughout the entire product's code? Or is it located in a discreet section of code?

Also, how easily can the OSS be removed? Can the integrated OSS simply be cut out and patched, or does an entire section of code need to be rewritten? Situations can be further complicated if products comprising OSS are the subject of ongoing commercial negotiations. While such negotiations can often be saved, it will likely come at a cost to the company marketing the product containing OSS.

CONCLUSION

As issues relating to OSS become increasingly prevalent for life science innovations, it is important for life sciences companies to realize the types of problems OSS can cause, how to spot them, and how to address them. While the problems caused by OSS can almost always be remedied given a sufficient amount of time, it is important for life sciences companies to confront any issues sooner rather than later to avoid pitfalls along the road to a highly anticipated product launch.

Notes

1. Open Source Initiative, Frequently Asked Questions, *https://opensource.org/faq#osd* (last visited Feb. 18, 2022).
2. Chris Hoffman, What is Open Source Software, and Why Does It Matter?, How-To Geek, *https://www.howtogeek.com/129967/htg-explains-what-is-open-source-software-and-why-you-should-care/* (Sept. 26, 2016).
3. *Id*.