Verne, B. Michael

From:

Sent: Monday, August 25, 2008 10:46 AM

To: Verne, B. Michael

Subject: CONFIDENTIAL -- HSR reportability regarding an IP license

Mike,

I would appreciate your guidance on a question regarding HSR reportability with respect to acquisition of an IP license relating to an active pharmaceutical ingredient ("API"). The proposed license from patent holder A would grant exclusive right to company B manufacture the API and exclusive right to sell the API in the US. Licensor A would retain rights to promote and also the right to develop the API under the patent (which development right I understand to mean that licensor A is responsible for seeing the pharmaceutical product through FDA approval). Would retention by A of co-promotion rights and development rights in the US be sufficient to render the license non-exclusive for HSR reporting purposes? Or does the question of license exclusivity really come down to whether there has been an exclusive grant of manufacturing rights within the territory?

Informal opinions I have seen which discuss retention of rights by the licensor to co-promote also appear to involve the licensor's retention of some manufacturing rights (which is not the case here, at least not within the US territory). See, e.g.,

http://www.ftc.gov/bc/hsr/informal/opinions/0601012.htm http://www.ftc.gov/bc/hsr/informal/opinions/0709013.htm

Your prompt advice would be greatly appreciated. Please feel free to call me at the number below if it would make sense to discuss.

Many thanks,



This is still AN Excession
Usesuse For HSA-PUAPOSES.

8/28/08

K.WALSH CONCUAS.