

## Pain and King Start the Countdown

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**Pain Therapeutics** (Nasdaq: [PTIE](#)) and marketing partner **King Pharmaceuticals** (NYSE: [KG](#)) have now started the clock on perhaps the most precarious period yet for their lead drug candidate, Remoxy.

Pain and King announced yesterday that they had submitted a marketing application to the FDA for the abuse-deterrent oxycodone pain drug, starting the countdown toward the agency's review.

Assuming the FDA accepts the filing as a 505(b)2 -- a change to an existing drug -- an even more important clock also starts. Rival drugmaker Purdue Pharma, maker of the similar OxyContin, can attempt to stall the Remoxy FDA with a patent challenge any time within the next 45 days.

Pain and King have always vigorously proclaimed that Remoxy does not infringe upon Purdue's OxyContin patents -- called a paragraph IV certification -- but that doesn't necessarily preclude Purdue from (rightfully or wrongfully) suing them.

If Purdue does file a lawsuit, the FDA won't approve Pain and King's Remoxy marketing application until 30 months after the lawsuit is filed or the patent challenge litigation is concluded, whichever occurs first. (Investors wanting to hedge against this near-term patent challenge risk can always use put options.)

Whatever happens with the Remoxy patent situation, most of the abuse-deterrent drugmakers [received good news last month](#), after an advisory panel meeting sounded a relatively favorable note about this emerging class of drugs.

Purdue Pharma is in the [lead](#); it will be the first drugmaker to get an approval decision on its own abuse-deterrent version of OxyContin. If Purdue fails to gain FDA approval at its marketing application review later this year, Pain and King will be back in the drivers seat (assuming no patent challenges), now that **Alpharma** (NYSE: [ALO](#)) also had to delay its own abuse-deterrent opioid marketing application.

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