

Did A Melatonin Patent Inspire Current Dose Confusion?

Posted on July 12, 2018 by Scott Alexander



Yesterday [I wrote about melatonin](#), mentioning that most drugstore melatonin supplements were 10x or more the recommended dose. A commenter on Facebook pointed me to an interesting explanation of why.

Dr. Richard Wurtman, an MIT scientist who helped discover melatonin's role in the body and pioneer its use as a sleep aid, [writes](#):

MIT was so excited about our research team's melatonin-sleep connection discovery that they decided to patent the use of reasonable doses of melatonin—up to 1 mg—for promoting sleep.

But they made a big mistake. They assumed that the FDA would want to regulate the hormone and its use as a sleep therapy. They also thought the FDA wouldn't allow companies to sell melatonin in doses 3-times, 10-times, even 15-times more than what's necessary to promote sound sleep.

Much to MIT's surprise, however, the FDA took a pass on melatonin. At that time, the FDA was focusing on other issues, like nicotine addiction, and they may have felt they had bigger fish to fry.

Also, the FDA knew that the research on melatonin showed it to be non-toxic, even at extremely high doses, so they probably weren't too worried about how consumers might use it. In the end, and as a way of getting melatonin on to the market, the FDA chose to label it a dietary supplement, which does not require FDA regulation. Clearly, this was wrong because melatonin is a hormone, not a dietary supplement.

Quickly, supplement manufacturers saw the huge potential in selling melatonin to promote good sleep. After all, millions of Americans struggled to get to sleep and stay asleep, and were desperate for safe alternatives to anti-anxiety medicines and sleeping pills that rarely worked well and came with plenty of side effects.

Also, manufacturers must have realized that they could avoid paying royalties to MIT for melatonin doses over the 1 mg measure. So, they produced doses of 3 mg, 5 mg, 10 mg and more! Their thinking—like so much else in our American society—was likely, “bigger is better!” But, they couldn't be more wrong.

So he's saying that... in order to get around a patent on using the correct dose of melatonin... supplement manufacturers... used the

wrong dose of melatonin? I enjoy collecting stories of [all the crazy perversities](#) created by our current pharmaceutical system, but this one really takes the cake.

Assuming it's true, that is. Commenter Rodrigo [brings up](#) some reasons to be suspicious:

1. Who would patent a drug only up to a certain dose? Isn't this really dumb?
2. To avoid the patent on the correct dose, drugstores just have to sell more than 1 mg – for example, 2 mg. But they actually sell up to 10 mg.

To these I would add:

1. Lots of supplements are very high dose. When I Google Vitamin C, the [first product](#) that comes up advertises that it has 1111% of the recommended daily allowance, which seems better optimized for numerological purposes than medical ones.
2. A few companies do sell melatonin at the right dose range, and MIT hasn't sued them yet.

Normally I would find these considerations pretty persuasive, but I feel like the guy who discovered melatonin and ran a pharmaceutical company for a while knows more about the history of melatonin and pharmaceutical regulations than I do.

From [last week](#):

This kind of thing is the endless drudgery of rationality training... questions like “How much should you discount a compelling-sounding theory based on the bias of its inventor?” And “How much does someone being a famous expert count in their favor?” And “How concerned should we be if a theory seems to violate efficient market assumptions?” And “How do we balance arguments based on what rationally has to be true, vs. someone’s empirical but fallible data sets?”

Here I’m just really skeptical of the MIT patent story. Wurtman seems to admit that “bigger is better” played a role. Maybe the patent thing was a very small issue, around the beginning of melatonin sales, and was soon forgotten – but the tradition of expecting melatonin to be very high dose stuck around forever, mostly for other reasons?

EDIT: Commenters, including a patent lawyer, have filled in the rest of the story. Because melatonin is a natural hormone and not an invention, patents can only cover specific uses of it. The MIT patent covered the proper way to use it for sleep; a broader patent might not have been granted. The patent probably guided supplement companies, but expired about five years ago. It’s now legal to produce melatonin 0.3 mg pills, but people are so used to higher doses that few people do.