Arguments Made By Petitioner in PGR2019-00048 and in the District Court Litigation

PGR2019-00048	The District Court Litigation
"Claims 1-13 Would Have Been Obvious Over The Korlym Label, Lee, and FDA Guidance." Pet. at 42.	"Claims 1-13 are invalid as obvious under 35 U.S.C. § 103 over the 2012 Korlym Label and Lee, optionally in combination with 2006 FDA guidance." Invalidity Contentions at 190.
"[A] skilled artisan would have had a reasonable expectation that 600 mg could be administered safely, even in combination with a strong CYP3A inhibitor." Pet. at 33.	"[A] skilled artisan would have had a reasonable—while not absolute—expectation that 600 mg could be administered safely, even in combination with a strong CYP3A inhibitor." Invalidity Contentions at 194.
"Nor would the 300-mg-per-day dose limitation on the Korlym Label have discouraged a skilled artisan from titrating the dose to 600 mg when used in combination with strong CYP3A inhibitors." Pet. at 35	"Nor would the 300-mg-per-day dose limitation on the 2012 Korlym Label have discouraged a skilled artisan from titrating the dose to 600 mg when used in combination with strong CYP3A inhibitors." Invalidity Contentions at 195.
"That is why the FDA instructed Corcept to do a clinical study: 'to get a quantitative estimate of the change in exposure of mifepristone following co-administration with ketoconazole.'" Pet. at 35-36.	"That is why the FDA instructed Corcept to do a clinical study: 'to get a quantitative estimate of the change in exposure of mifepristone following co-administration with ketoconazole.'" Invalidity Contentions at 196.
"[A] skilled artisan would have known based on the label and Lee that the once-daily 600 mg dose was reasonably likely to work, and the skilled artisan would have been able and motivated to test whether the 600-mg dose would work by running a clinical DDI study." Pet. at 37.	"[A] skilled artisan would have known based on the label and Lee that the once-daily 600 mg dose was reasonably likely to work, and the skilled artisan would have been able and motivated to test that hypothesis by running a clinical study." Invalidity Contentions at 197.
"During prosecution, Corcept effectively conceded that the '214 patent claims were prima facie obvious in light of the teachings of the Korlym Label." Pet. at 46-47.	"During prosecution, Corcept effectively conceded that the '214 patent claims were prima facie obvious in light of the teachings of the 2012 Korlym Label." Invalidity Contentions at 203.
"[A]ny clinician familiar with the Korlym Drug Approval Package would have known that there were not necessarily any concerns over toxicity." *See* Pet. at 49	"[A]ny clinician familiar with the Korlym Drug Approval Package would have known that there were not necessarily any concerns over toxicity." Invalidity Contentions at 204.

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"[T]he FDA fully expected that co-administration (at some dose) would be safe and effective—it just did not know what precise dose that was." Pet. at 49.	"[T]he FDA fully expected that co-administration (at some dose) would be safe and effective—it just did not know what precise dose that was." Invalidity Contentions at 204.
A "clinician would have known that, while caution was surely warranted in co-administering the drugs, there was nothing wrong with titrating the dose above 300 mg." Pet. at 49.	A "clinician would have known that, while caution was surely warranted in co-administering the drugs, there was nothing wrong with titrating the dose above 300 mg." Invalidity Contentions at 204.
"Corcept's statement that 300 mg mifepristone was unlikely to be effective betrays a misunderstanding of the basic idea of drug-drug interactions." Pet. at 53.	"Corcept's point (1)—that 300 mg mifepristone was unlikely to be effective—betrays a misunderstanding of the basic idea of drug-drug interactions." Invalidity Contentions at 206.
"[E]ven if a 300-mg-per-day dose of mifepristone administered alone were insufficient to achieve therapeutic efficacy, it would not follow that a 300-mg-day-dose in combination with a CYP3A inhibitor would be insufficient." Pet. at 53-54.	"[E]ven if a 300-mg-per-day dose of mifepristone administered alone were insufficient to achieve therapeutic efficacy, it would not follow that a 300-mg-day-dose in combination with a CYP3A inhibitor would be insufficient." Invalidity Contentions at 206.