

APPENDIX
Excerpt From Jury Instructions Regarding Enablement
(Dkt. No. 475 ¶¶ 40–46)

40. The next defense is called lack of enablement. This relates to whether the patent specification and figures, as originally filed, disclosed the claimed inventions in a way that enabled those skilled in the art to make and use them.

41. With respect to the question of enablement, the Patent Act provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

42. To prove invalidity by reason of non-enablement, defendant Hologic must prove that the asserted claims are invalid by showing that the patent specification and figures, as originally filed, failed to contain a description of the claimed invention sufficiently full and clear to enable a person of ordinary skill in the field to make and use the full scope of the asserted claims without undue experimentation. The purpose of the enablement requirement is to make sure that a patent specification and figures, as originally filed, disclosed how to practice the full invention in return for the limited monopoly granted by the government to the inventor. The question of whether a patent is enabling is judged as of the date the original application for the patent was first filed. It is presumed that all relevant prior art was already known to those practicing in the field.

43. Even disclosure of a single example in a specification can sometimes support the full scope of a claim. On the other hand, disclosure of one example for carrying out a claimed method does not necessarily entitle an inventor to a broad generic claim covering any and all means for achieving its objective. Whether or not claims 37 and 38 were enabled is a question for you the jury to decide based on the trial evidence, the critical question being whether the specification and drawings, when combined with all prior art known to those skilled in the art, disclosed how to practice the full scope of the asserted inventions as claimed without having to undertake excessive experimentation.

44. In determining whether excessive experimentation would have been required, you may consider the following factors:

1. the scope of the claimed invention;
2. the amount of guidance presented in the patent;
3. the amount of experimentation necessary;
4. the time and cost of any necessary experimentation;

5. how routine any necessary experimentation was in the field;
6. whether the patent disclosed specific working examples of the claimed invention;
7. the nature and predictability of experimentation and variations of the field; and
8. the level of ordinary skill in the field.

45. I will now elaborate on some of these factors. With respect to the first factor, the scope of the claimed invention, a patentee who chooses broad claim language must make sure the broad claims are fully enabled. The scope of the claims must be less than or equal to the scope of the enablement to ensure that public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. Put differently, the narrower the claims, the easier it is to sustain enablement.

As stated, you may consider the predictability of experiments and variations in the field. You may consider whether the invention pertains to an art where the results of variations and/or experiments were predictable, such that variations on the embodiments disclosed in the specification would have been predictable.

46. By analogy, suppose that an inventor created a particular method for fuel efficiency and described the method in such detail in the specification that a person of ordinary skill in the art would be able to achieve fuel efficiency. Although the specification would meet the requirements of enablement with respect to a claim directed to that particular method, it would not necessarily support a broad claim to every possible type of method to achieve fuel efficiency no matter how different in operation from the claimed invention. A single embodiment would support such a generic claim only if the specification would enable a person skilled in the art to use the full scope of the claimed invention at the time of application without undue experimentation.

In our case, a question for you is whether defendant Hologic has proven that the specification and figures failed to enable the full scope of claims 37 and 38 asserted by plaintiff Conceptus.