

MASS. INST. OF TECH. v. SHIRE PHARMACEUTICALS, Appeal No. 2015-1881  
(Fed. Cir. October 13, 2016). Before O'Malley, Chen, and Stoll. Appealed from D. Mass.  
(Judge Wolf).

Background:

MIT sued Shire alleging infringement of two patents directed to three-dimensional, synthetic, biodegradable structures for growing tissues for vascularized organs, and methods for creating the structures. Shire's accused product is used to grow the vascularized portion of skin to treat diabetic foot ulcers.

During prosecution, MIT attempted to overcome prior art rejections by limiting the claims to "non-skin organ cells," or to the thickness of the claimed cell mass being "greater than 300 microns." However, the amendments were deleted after being rejected under 35 U.S.C. §112(a). The claims were then amended to be directed to "vascularized organ tissue" and to include "cells derived from a vascularized tissue," and arguments were made that the prior art could not produce vascularized tissues and organs. The claims were then allowed.

Shire argued that MIT's arguments during prosecution disclaimed skin from the scope of MIT's claims. The district court disagreed, finding that Shire infringed MIT's patents.

Issue/Holding:

Does prosecution history disclaimer apply? No, affirmed.

Discussion:

The doctrine of prosecution disclaimer precludes patentees from recapturing, through claim interpretation, specific meanings disclaimed during prosecution. In order for prosecution disclaimer to apply, the disavowal must be both clear and unmistakable.

The Federal Circuit agreed with the district court that there was no clear and unmistakable disavowal of skin as it related to the terms "vascularized organ tissue" and "cells derived from a vascularized tissue." The Federal Circuit found that MIT's previous arguments were directed towards features that were not in the patented claims, and there was no evidence that the previous arguments were meant to apply to the patented terms.

Therefore, the Federal Circuit concluded that prosecution history disclaimer does not apply, and that the vascularized portion of skin is included within the scope of the terms "vascularized organ tissue" and "cells derived from a vascularized tissue."