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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,

Petitioner,

v.

NOVARTIS AG,

Patent Owner.

Case IPR2016-01059

Patent No. 5,665,772

**PATENT OWNER'S PRELIMINARY
RESPONSE UNDER 37 C.F.R. § 42.107**

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<i>Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC.</i> , 579 Fed. Appx. 996 (Fed. Cir. 2014)	15
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Other Authorities

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37 C.F.R. § 42.10816

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