

## Biotech Patent Held Invalid For Failing to Disclose Preferred Host Cells

Written by DeAnn F. Smith, Jeremy A. Younkin

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On March 8, 2010, the Federal Circuit affirmed a ruling of the International Trade Commission invalidating the asserted claims of two U.S. patents for failure to meet the best mode requirement. *Ajinomoto Co., Inc. v. ITC*, available here. Foley Hoag represented the prevailing party, Global Bio-Chem Technology Group Company Limited (GBT), a Chinese biotechnology company. The patents covered the production of lysine using genetically modified bacteria.

The case is important because it casts a spotlight on the “best mode” requirement unique to U.S. patent law. While the Patent Act requires inventors to describe their inventions, it also requires that they disclose their “best mode” of practicing the claimed invention. As the Federal Circuit articulated the rationale for the doctrine, inventors are prohibited from “receiving the benefit of the right to exclude while at the same time concealing from the public preferred embodiments of their inventions.” Thus, one cannot obtain a patent on an invention while seeking to maintain aspects of the invention as a trade secret. Here, the Federal Circuit held that “[t]he inventors could not, consistent with the best mode requirement, claim the cultivation of a bacterium containing an *ldc* mutation while simultaneously keeping from the public the identity of the one and only bacterium they used to practice that cultivation.”

Inventors, particularly foreign entities, must be aware of the best mode requirement so that they do not file U.S. applications that are invalid because they have failed to make an adequate disclosure. Here, the Federal Circuit ruled that “[t]o satisfy the best mode requirement, an inventor must disclose the preferred embodiment of his invention as well as preferences that materially affect the properties of the invention.” Biotechnology companies must be mindful of this case, because it underscores the importance of disclosing preferred host strains in patents that include claims drawn to producing a desired end product (for example, a therapeutic protein) by culturing cells.

The case is also notable because the Federal Circuit rejected the patentee’s argument that the best mode requirement is limited to the “innovative aspects” or “inventive features” of the invention.

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