

# United States Court of Appeals for the Federal Circuit

2009-1081

AJINOMOTO CO., INC.  
and AJINOMOTO HEARTLAND LLC,

Appellants,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

and

GLOBAL BIO-CHEM TECHNOLOGY GROUP COMPANY LIMITED,  
CHANGCHUN DACHENG BIO-CHEM ENGINEERING DEVELOPMENT CO., LTD.,  
CHANGCHUN BAOCHENG BIO-CHEM DEVELOPMENT CO., LTD.,  
CHANGCHUN DAHE BIO TECHNOLOGY DEVELOPMENT CO., LTD.,  
and BIO-CHEM TECHNOLOGY (HK) LIMITED,

Intervenors.

Joseph M. Malkin, Orrick, Herrington & Sutcliffe LLP, of San Francisco, California, argued for appellants. Of counsel were E. Joshua Rosenkranz and Alex V. Chachkes, of New York, New York, and Kurt T. Mulville, of Irvine, California.

James A. Worth, Attorney, Office of the General Counsel, United States International Trade Commission, of Washington, DC, argued for appellee. With him on the brief were James M. Lyons, General Counsel, and Wayne W. Herrington, Assistant General Counsel.

Claire Laporte, Foley Hoag LLP, of Boston, Massachusetts, argued for intervenors. With her on the brief were DeAnn F. Smith, Jeremy A. Younkin, and Marco J. Quina. Of counsel on the brief were Ruixue Ran, East Associates Law Firm, of Beijing, China, and Tom M. Schaumberg and Sarah E. Hamblin, Adduci, Mastriani & Schaumberg LLP, of Washington, DC.

Appealed from: United States International Trade Commission

# United States Court of Appeals for the Federal Circuit

2009-1081

AJINOMOTO CO., INC.,  
and AJINOMOTO HEARTLAND LLC,

Appellants,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

and

GLOBAL BIO-CHEM TECHNOLOGY GROUP COMPANY LIMITED,  
CHANGCHUN DACHENG BIO-CHEM ENGINEERING DEVELOPMENT CO., LTD.,  
CHANGCHUN BAOCHENG BIO-CHEM DEVELOPMENT CO., LTD.,  
CHANGCHUN DAHE BIO TECHNOLOGY DEVELOPMENT CO., LTD.,  
and BIO-CHEM TECHNOLOGY (HK) LIMITED,

Intervenors.

On appeal from the United States International Trade Commission in  
Investigation No. 337-TA-571.

---

DECIDED: March 8, 2010

---

Before NEWMAN, LOURIE, and LINN, Circuit Judges.

LOURIE, Circuit Judge.

Ajinomoto Co., Inc. and Ajinomoto Heartland LLC (collectively, "Ajinomoto") appeal from the final determination of the International Trade Commission ("Commission") that the importation and sale of certain lysine feed products did not violate section 337 of the Tariff Act of 1930 as amended, 19 U.S.C. § 1337. The

Commission found that (1) the asserted claims of Ajinomoto's U.S. Patents 5,827,698 ("the '698 patent") and 6,040,160 ("the '160 patent") are invalid under 35 U.S.C. § 112 for failure to comply with the best mode requirement and (2) the '698 patent is unenforceable due to inequitable conduct. We affirm.

## BACKGROUND

### I.

The '698 and '160 patents relate to improved methods of producing L-lysine ("lysine") by cultivating Escherichia bacteria that have been genetically engineered to produce and accumulate greater quantities of lysine than naturally occurring (or wild-type) bacterial strains. Lysine is an essential amino acid, which means that most animals cannot synthesize it but must obtain it directly from their diets. Consequently, feed producers and farmers regularly add lysine as a necessary dietary supplement to low-protein grass feed for livestock. To supply this billion dollar, worldwide market for lysine, the industry employs microorganisms such as Escherichia coli ("E. coli") that can synthesize lysine from a carbon source (e.g., a sugar such as glucose) through a well-known biosynthetic pathway.

In nature, E. coli produce and accumulate only small amounts of lysine for their own nutrition. This low-level production limits the amount of lysine that can be collected from its cultivation. The patents involved in this case alter two mechanisms that contribute to E. coli's limited lysine production. The first mechanism, known as "feedback inhibition," is triggered by lysine itself. Specifically, when sufficient lysine is present to meet the organism's needs, lysine inhibits its own production by inhibiting the activity of certain of its biosynthetic enzymes. At the same time, E. coli also employ

enzymes, called lysine decarboxylases, which break down any extra lysine produced into a non-nutritious byproduct. Both mechanisms—feedback inhibition and lysine degradation—keep E. coli from accumulating excess lysine.

Scientists at Ajinomoto disrupted the lysine degradation limitation imposed on lysine production by engineering an E. coli with a mutant lysine decarboxylase gene. Specifically, the '698 patent, entitled “Lysine Decarboxylase Gene and Method of Producing L-Lysine,” discloses the identification of the lysine decarboxylase gene ldc and the creation of an E. coli strain with mutations in ldc that reduce or eliminate lysine decarboxylase activity. Asserted claim 15 of the '698 patent covers a method of producing lysine by cultivating E. coli with mutant ldc and collecting the accumulated lysine. The asserted claim, rewritten to include the claims from which it depends, reads as follows:

15. A method for producing L-lysine, comprising:
  - (a) cultivating an isolated microorganism belonging to the genus *Escherichia*, wherein the microorganism contains a [mutant lysine decarboxylase] in a liquid medium, thereby producing the L-lysine and accumulating the L-lysine in the liquid medium, and
  - (b) collecting the L-lysine produced and accumulated in step (a), wherein the microorganism belongs to the species *Escherichia coli*.

The '698 patent claims priority from a Japanese application filed on December 9, 1994, and issued on October 27, 1998.

Scientists at Ajinomoto similarly affected the feedback inhibition limitation imposed on lysine production by engineering an E. coli with a mutant lysine biosynthetic enzyme. Specifically, the '160 patent, entitled “Method of Producing L-Lysine by Fermentation,” discloses the creation of an E. coli strain with at least one of two mutations in dapA, the gene encoding the biosynthetic enzyme dihydrodipicolinate

synthase (“DDPS”). The mutations release DDPS from the feedback inhibition imposed by excess lysine, and result in an E. coli strain that produces greater amounts of lysine than wild-type strains. Asserted claim 15 of the ’160 patent covers a method of producing lysine by cultivating E. coli that contain mutant dapA and collecting the accumulated lysine. The asserted claim, rewritten to include the claim from which it depends, reads as follows:

15. A method of producing L-lysine, comprising: cultivating a bacterium belonging [to] the genus Escherichia which is transformed with a DNA coding for a dihydrodipicolinate synthase originating from a bacterium belonging to the genus Escherichia and having mutation to desensitize feedback inhibition of L-lysine, wherein the mutation is selected from the group consisting of [a mutation to replace the alanine residue at the 81st position and/or a mutation to replace the histidine residue at the 118th position] in a suitable culture medium, producing and accumulating L-lysine in the culture thereof, and collecting L-lysine from the culture.

The ’160 patent was originally filed in Japan on December 8, 1993, and subsequently filed in the United States through the Patent Cooperation Treaty (“PCT”) on November 28, 1994. It entered the national phase in the United States on June 9, 1997, and issued as the ’160 patent on March 21, 2000.

Both patents disclose certain E. coli host strains for practicing the claimed inventions. Specifically, the ’698 patent describes a two-step process of producing a mutant ldc host strain. ’698 patent, col.8 l.40–col.9 l.42. The first step subjects a wild-type E. coli strain, W3110, to NTG mutation/AEC selection to identify a strain having lysine productivity. Id. col.8 ll.40-63; see also col.5 ll.20-43. The specification identifies that strain as WC196 and indicates that the inventors deposited WC196 in an international depository. Id. col.8. ll.57-63; see also col.5 ll.34-43. In the second step the mutant ldc gene is inserted into the WC196 strain to create the ldc mutant strain,

identified as WC196L. Id. col.9 ll.23-42. In contrast to the disclosure in the specification, it is undisputed that the actual strain used by the inventors had two additional genetic alterations made to it before the addition of mutant ldc. Specifically, the inventors first modified the wild-type W3110 strain to insert a variant lysC, a gene encoding an enzyme in the lysine biosynthesis pathway. The inventors identified this strain as WC80. Then, following the NTG mutation/AEC selection step, which resulted in the strain WC80-196, the inventors inserted sucrose utilization genes into the E. coli to permit the resulting strain to use sucrose as a carbon source. The inventors identified this host strain as WC80-196S. Only then did the inventors insert the ldc mutation into the WC80-196S host strain.

Similarly, the '160 patent discloses two host strains, B-399 and W3110(tyrA), into which the inventors introduced mutant dapA. '160 patent, col.27 ll.10-11, col.29 l.43. Yet, before filing the Japanese application from which the '160 patent claims priority, the inventors characterized a different strain, AE-70, as their best lysine producer.

## II.

On April 25, 2006, Ajinomoto filed a complaint at the Commission alleging a violation of section 337 in the importation and sale of certain lysine feed products made by the methods claimed in the '698 and '160 patents. The complaint named Global Bio-Chem Technology Group Company Limited; Changchun Dacheng Bio-Chem Engineering Development Co., Ltd.; Changchun Baocheng Bio-Chem Development Co., Ltd.; Changchun Dahe Bio Technology Development Co., Ltd.; and Bio-Chem Technology (HK) Limited (collectively, "GBT") as respondents. On May 24, 2006, the Commission initiated an investigation based on Ajinomoto's complaint. 71 Fed. Reg.

30,958 (May 31, 2006). Before trial, GBT admitted infringement of both patents with regard to the importation and sale of lysine made by a certain bacterial strain.

On July 31, 2008, the Administrative Law Judge (“ALJ”) rendered his initial determination, finding no violation of section 337. Specifically, the ALJ found that the asserted claims were invalid for multiple violations of the best mode requirement of 35 U.S.C. § 112, first paragraph, and that both patents were unenforceable for inequitable conduct because of those best mode violations.

For the best mode analysis, the ALJ first defined the scope of the claims. The ALJ concluded that the inventions encompassed not just the claimed genetic mutations in the ldc and dapA genes, respectively, but the overall production of lysine, including (1) cultivating the genetically engineered E. coli host strain in a suitable culture medium, (2) producing and accumulating lysine in the culture, and (3) collecting lysine from the culture. Then, with regard to claim 15 of the '698 patent, the ALJ concluded that the inventors had violated the best mode requirement by (1) concealing their preferred and only host strain, WC80-196S, via a misrepresentation of the steps actually performed to create a mutant ldc host strain; (2) concealing sucrose as their preferred carbon source, which materially affects achieving the claimed invention; and (3) submitting data associated with fictitious host strains in support of the best mode. Similarly, with regard to claim 15 of the '160 patent, the ALJ concluded that the inventors had violated the best mode requirement by (1) concealing their preferred host strain, AE-70, and (2) submitting fictitious data in support of the best mode.

The ALJ next held both patents unenforceable for inequitable conduct. For both patents, the ALJ found that materiality was established by the best mode violations and

that intent to deceive was established by the inventors' intentional inclusion of fictitious data coupled with their failure to disclose their preferred strains and, with respect to the '698 patent, carbon source at a time when Ajinomoto was facing increased business competition from another lysine supplier. The ALJ then, in weighing materiality and intent, concluded that equity demanded a finding of inequitable conduct because both prongs were established to a high degree.

Ajinomoto petitioned the Commission for review. On September 29, 2008, the Commission issued notice that it had chosen to review but had taken no position on the ALJ's finding that (1) claim 15 of the '160 patent is invalid for failure to meet the best mode requirement to the extent that the finding was based on fictitious data and (2) the '160 patent is unenforceable for inequitable conduct. The Commission did not review the remainder of the ALJ's determination, making it the Commission's final determination of no violation of section 337. See Beloit Corp. v. Valmet Oy, 742 F.2d 1421, 1422-23 (Fed. Cir. 1984).

Ajinomoto timely appealed. We have jurisdiction pursuant to 19 U.S.C. § 1337(c) and 28 U.S.C. § 1295(a)(6).

## DISCUSSION

We review the Commission's final determination of no violation of section 337 under the standards of the Administrative Procedure Act. See 19 U.S.C. § 1337(c) (stating that a party adversely affected by a section 337 determination may appeal to this court "for review in accordance with chapter 7 of Title 5"). Under the Act, this court reviews the Commission's legal determinations, including the legal standard to be applied, de novo, and its factual findings for substantial evidence. See 5 U.S.C.



§ 706(2)(A)(E); SKF USA Inc. v. Int'l Trade Comm'n, 423 F.3d 1307, 1312 (Fed. Cir. 2005).

I.

Section 112 of the Patent Act provides that the patent specification “shall set forth the best mode contemplated by the inventor of carrying out his invention.” 35 U.S.C. § 112, ¶ 1. Known as the best mode requirement, it comprises part of the quid pro quo of the patent grant, prohibiting inventors from receiving the benefit of the right to exclude while at the same time concealing from the public preferred embodiments of their inventions. See Teleflex, Inc. v. Ficoso N. Am. Corp., 299 F.3d 1313, 1330 (Fed. Cir. 2002). Compliance with the best mode requirement is a question of fact, but the scope of the invention to which the best mode applies is a question of law, which we review de novo. See Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306, 1312, 1320 (Fed. Cir. 2002).

To 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. See id. at 1319. The disclosure requirement, however, is limited to “the invention defined by the claims.” Id. at 1315; see also Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1567 (Fed. Cir. 1996). Subject matter outside the scope of the claims falls outside of the best mode requirement. AllVoice Computing PLC v. Nuance Commc'ns, Inc., 504 F.3d 1236, 1246-48 (Fed. Cir. 2007). Accordingly, we have held that a threshold step in a best mode inquiry is to define the invention by construing the claims. Bayer, 301 F.3d at 1320 (citing N. Telecom Ltd. v. Samsung Elec. Co., 215 F.3d 1281, 1286-87 (Fed. Cir. 2000)).

Once the invention is defined, determining compliance with the best mode requirement is a two-prong inquiry. First, the court must determine whether, at the time the patent application was filed, the inventor possessed a best mode of practicing the claimed invention. United States Gypsum Co. v. Nat'l Gypsum Co., 74 F.3d 1209, 1212 (Fed. Cir. 1996). This prong is highly subjective; it focuses on the inventor's own personal preferences as of the application's filing date. N. Telecom, 215 F.3d at 1286. Second, if the inventor has a subjective preference for one mode over all others, the court must then determine whether the inventor "concealed" the preferred mode from the public. Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 928 (Fed. Cir. 1990)). In other words, the second prong asks whether the inventor's disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention. Id. This second inquiry is objective; it depends upon the scope of the claimed invention and the level of skill in the relevant art. Id.

On appeal, Ajinomoto does not challenge the Commission's factual findings that the inventors had subjective preferences for particular subject matter and that the asserted patents' lack of disclosure concealed certain of that subject matter. Specifically, Ajinomoto does not contest that (1) the inventors had a best host strain for practicing claim 15 of the '698 patent, WC80-196S, which they failed to disclose and deposit and which contained two additional genetic modifications not disclosed in the specification; (2) the inventors had a best host strain for practicing claim 15 of the '160 patent, AE-70, which they failed to disclose; (3) the inventors preferred but failed to disclose sucrose as a carbon source for practicing the '698 patent; and (4) the inventors identified their host strains by different names than those disclosed in the '698 patent's

specification. Ajinomoto instead alleges that the Commission made multiple legal errors in defining the scope of its claimed inventions and the scope of the best mode requirement. We address each in turn.

A.

Ajinomoto first argues that the Commission erred in defining “best” in terms of the “overall production of lysine” rather than in terms of the claimed invention. Specifically, Ajinomoto contends that the Commission erred in applying the best mode requirement beyond the patents’ “innovative aspects”—the claimed genetic mutations in ldc or dapA—and applying it to cover unrelated and non-novel subject matter, including the creation and use of unclaimed host strains and, for the ’698 patent, an unclaimed carbon source. That analysis, according to Ajinomoto, conflicts with this court’s holding that the best mode requirement is a “two-way street,” for which a patentee’s obligations are no broader than the right to exclude.

The government and GBT respond that the best mode inquiry relates to the claimed invention, not just to its “inventive aspects,” as Ajinomoto contends. Thus, according to the government and GBT, the Commission correctly defined the claimed invention as a process for making lysine in culture medium using a genetically altered E. coli bacterium and, as a result, correctly held that the best mode of carrying out that claimed process encompassed not only the ldc or dapA mutations but also the host strains and carbon sources used.

We agree with the government and GBT that Ajinomoto misstates the law. As discussed above, while not every preference constitutes a best mode for purposes of § 112, the preferred embodiment of the invention must be disclosed. Bayer, 301 F.3d at

1319. Again, the invention is the invention claimed. Zygo, 79 F.3d at 1567. It is not limited, as Ajinomoto asserts, to vague “innovative aspects” or “inventive features” of the invention, terms that appear nowhere in our best mode case law.

We also agree that, focusing on the inventions recited in the asserted claims, the Commission correctly included within the scope of the best mode requirement an obligation to disclose the inventors’ preferred host strains. Both of the asserted claims relate to methods of producing lysine by cultivating genetically engineered Escherichia bacteria. Claim 15 of the ’698 patent recites a “method for producing L-lysine,” the method comprising “cultivating an isolated microorganism” of the species Escherichia coli containing mutant ldc. Similarly, claim 15 of the ’160 patent recites a “method of producing L-lysine,” the method comprising “cultivating a bacterium belonging [to] the genus Escherichia” containing mutant dapA. Thus, the scope of the invention as defined by the claims covers more than the specific ldc and dapA mutations; the invention includes the cultivation of a bacterial host strain containing those mutations.\*

By defining the invention to include the host strains, we do not read the Commission’s decision as requiring the disclosure of any and all preferences related to the production of lysine, as Ajinomoto claims. The Commission simply defined the scope of the claimed invention to include “cultivating a bacterium” as recited by the asserted claims. Also, the Commission did not, as Ajinomoto asserts, require the

---

\* Faced with a similar claim to “culturing a salinomycins-producing Streptomyces microorganism,” we rejected the patentee’s argument that the claim did not encompass the microorganism and concluded that the inventors did have an obligation under the best mode requirement to disclose their preferred host strain for carrying out the invention. Kaken Pharm. Co., v. Int’l Trade Comm’n, Nos. 96-1300, 96-1302, 1997 WL 152065, at \*2 (Fed. Cir. Mar. 31, 1997).

disclosure of all subject matter having to do with the claim term “bacterium.” The Commission simply required the disclosure of the preferred and, for the ’698 patent, only bacterial strain that the inventors used to practice the claimed invention.

Such an analysis does not, contrary to Ajinomoto’s assertion, conflict with the “two-way street” of the best mode obligation. See Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 964-67 (Fed. Cir. 2001) (holding that the best mode does not extend to unclaimed, non-novel subject matter). Ajinomoto argues that because it cannot exclude others from cultivating lysine-producing strains without the claimed ldc or dapA mutations, its best mode obligations extended only to those mutations. But Ajinomoto also cannot exclude others from using its mutations absent some bacterium and that bacterium’s cultivation. Infringement requires all claim limitations to be present, not just those that distinguish the claim from the prior art. So too with the best mode requirement, which applies to the invention claimed, with all its limitations, not just the novel ones. Ajinomoto claimed the right to exclude competitors from practicing a method of producing lysine by cultivating a bacterium with an ldc or dapA mutation. Thus, the “two-way street” of the best mode requirement obligated Ajinomoto to disclose its best bacterium for carrying out those inventions.

None of the cases on which Ajinomoto relies is to the contrary. Ajinomoto first cites Christianson v. Colt Industries Operating Corp., 822 F.2d 1544 (Fed. Cir. 1987), vacated on other grounds, 486 U.S. 800 (1988), in which the patents at issue claimed specific rifle parts. This court held that the best mode requirement did not extend to the production details for use of the claimed rifle parts in a particular weapon, the M-16, because the claims did not recite either the M-16 or interchangeability with M-16 parts.

Christianson, 822 F.2d at 1563. Rather, we explained, the claims related to the use of the rifle parts in any rifle. Id.

According to Ajinomoto, because the ldc and dapA mutations can be used in any E. coli, the inventors had no obligation to disclose their preferred E. coli strain, just as the inventors in Christianson had no obligation to disclose their preferred weapon, the M-16. We disagree. The claims in Christianson covered only specific rifle parts, not the weapons themselves. Even the claim quoted by Ajinomoto recites “[a]n improved . . . firearm” and claims only the improved rifle part—a bolt and carrier assembly. Ajinomoto’s asserted claims, in contrast, encompass more than the isolated ldc or dapA mutations, analogous to the rifle parts in Christianson; the claims encompass cultivating a bacterium containing such mutations, analogous to the weapon containing the rifle parts in Christianson. Thus, Ajinomoto’s undisputed preference for cultivating a particular bacterium constituted a best mode of carrying out the claimed invention, regardless whether the mutations could be used in other bacteria, and thus that preferred bacterium had to be disclosed.

Similarly, in AllVoice, Zygo, and Bayer, also cited by Ajinomoto, the claims as construed did not cover the embodiment alleged to have been concealed. The patent at issue in AllVoice involved an interface between a speech recognition system and various end-user applications. 504 F.3d at 1238. Asserted claim 73 recited forming a data link, and this court construed that claim as excluding the functionalities of updating or maintaining link accuracy. Id. at 1247-48. Accordingly, the court held that the updating and maintaining functionalities in the patentee’s commercial embodiment could not be a best mode of carrying out claim 73. Id. at 1248. Again in Zygo, the court

defined the claimed invention as an interferometer system that did not require packaging of any sort. 79 F.3d at 1567. The court thus held that the failure to disclose a commercial embodiment with packaging did not violate the best mode requirement. Id. at 1567-68. And finally, in Bayer, the court defined the claimed invention as the antibiotic product ciprofloxacin and held that an undisclosed process for making an unclaimed starting material did not constitute a best mode violation, as the unclaimed process did not materially affect the claimed antibiotic. 301 F.3d at 1322-23.

Here, in contrast, cultivating a host strain is claimed rather than unclaimed subject matter, and thus the inventors' preferred host strain had to be disclosed to comply with the best mode requirement. See, e.g., Gypsum, 74 F.3d at 1212-15 (finding a best mode violation for concealing the preferred expanded perlite for making the claimed joint compound comprising, inter alia, expanded perlite); Chemcast, 913 F.2d at 928-29 (finding a best mode violation for concealing the preferred material for making the claimed locking portion of a grommet). The disclosure requirement thus includes identifying, either by host name or method of preparation, other alterations (e.g., the lysC variant and sucrose utilization genes) that were part of the actual and only host strain into which the inventors inserted the claimed ldc mutant.

## B.

Alternatively, with regard to the '698 patent, Ajinomoto argues that even if the best mode requirement does extend to the bacterium used to practice claim 15, the Commission still erred as a matter of law in its application of the best mode requirement. Specifically, Ajinomoto first contends that the Commission erred in finding a best mode violation for the inventors' failure to disclose the unclaimed method of

creating the host strain into which they later inserted the patented ldc mutation. Furthermore, according to Ajinomoto, the inventors satisfied the best mode requirement by publicly depositing a strain containing the lysC variant and disclosing the deposit in the patent specification.

The government and GBT respond that Ajinomoto concealed the only bacterial strain altered to contain the patented ldc mutation, and thus the only embodiment of the claimed invention, by failing to identify it in any way, either by name or by its method of creation. Furthermore, they argue, the deposited strain was not in fact the preferred strain, WC80-196S, but a strain, WC80-196, which lacked the undisclosed sucrose utilization genes and which the inventors never used to practice the invention.

Again we disagree with Ajinomoto's interpretation of the Commission's opinion and the law. First, the Commission's opinion did not, as Ajinomoto contends, find that the inventors concealed the method of creating the host strain into which they later introduced an ldc mutation. Rather, the Commission found that the inventors concealed the identity of the preferred host strain, and specifically that other genetic alterations, including a lysC variant and sucrose utilization genes, had been introduced (by whatever method) into the only host strain used to practice the claimed invention. Cf. Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1347 (Fed. Cir. 2000) (finding no best mode violation when one of skill in the art would know that the identified preferred host strain contained another genetic alteration).

Second, the best mode requirement cannot be satisfied by the deposit of a non-preferred strain. It is undisputed that the host strain deposited by Ajinomoto lacked the sucrose utilization genes and thus was not the host strain into which the inventors



inserted an ldc mutation. Furthermore, while the deposited strain contained the lysC variant, the specification contains no disclosure of that fact, and one of skill in the art would not know that the strain had such an alteration. As such, the deposit failed to enable one of skill in the art to practice the inventors' preferred embodiment and thus concealed the best mode.

The 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. See Chemcast, 913 F.2d at 930 (“[W]here the inventor has failed to disclose the only mode he ever contemplated of carrying out his invention, the best mode requirement is violated.”). We thus affirm the Commission’s final determination of no violation of section 337 based on the invalidity of asserted claim 15 of the '698 patent for failure to disclose the inventors' best mode of carrying out the invention. As a result, we need not address the other best mode violations found by the Commission with regard to the '698 patent.

### C.

Finally, regarding the '160 patent, Ajinomoto also argues that the Commission erred in invalidating claim 15 based on a best mode violation because even if Ajinomoto did conceal its best host strain as of the filing date of its 1993 Japanese application, the only result is that Ajinomoto cannot rely on that application for priority purposes under 35 U.S.C. § 120. In other words, according to Ajinomoto, it is still entitled to the November 24, 1994, filing date of its PCT application and, by implication, a finding that GBT violated section 337 by infringing the '160 patent. Furthermore, Ajinomoto argues

that it did not waive its right to assert an alternative priority date for the '160 patent by first asserting it after trial because GBT, not Ajinomoto, had the burden of proof in challenging Ajinomoto's effective filing date.

Both the government and GBT respond that the Commission did not abuse its discretion in concluding that Ajinomoto had waived its right to rely on its PCT application's filing date by not raising the matter in its pre-trial brief as required by the ALJ's stated ground rules. The government further notes that Ajinomoto's express claim of priority from its 1993 application both limited the prior art on which GBT could rely for its invalidity defenses, thereby gaining an advantage for itself, and effectively concealed its best mode's priority date from the public.

We agree with the government and GBT. On its face, the '160 patent claims priority from a Japanese application filed on December 8, 1993, and Ajinomoto expressly relied on that claim in the Commission's investigation, raising no objection to GBT's proposed finding of fact that the effective filing date of claim 15 is December 8, 1993. Ajinomoto also does not contest the fact that it did not raise the issue of an alternative priority date for compliance with the best mode requirement until after trial. Thus, the Commission was well within its discretion to reject Ajinomoto's attempted bait-and-switch tactic. Ajinomoto's reliance on the December 8, 1993, priority date precluded GBT from offering in support of its invalidity defenses any relevant prior art published or otherwise made publicly available after December 8, 1993, but before the PCT application's November 28, 1994, filing date. It also failed to give GBT the opportunity to attack at trial Ajinomoto's PCT application's compliance with the best mode requirement. A patentee may seek to rely on an earlier priority date to overcome

intervening prior art, as did the patentee in Go Medical Industries Pty, Ltd. v. Inmed Corp., 471 F.3d 1264, 1270 (Fed. Cir. 2006), cited by Ajinomoto. A patentee may also argue in the alternative for different priority dates at trial. But a patentee cannot, as Ajinomoto attempts here, reverse a finding of invalidity by unveiling after trial an alternative priority date on which it would now like to rely.

Syngenta Seeds, Inc. v. Delta Cotton Co-op., Inc., 457 F.3d 1269 (Fed. Cir. 2006) is not to the contrary. In Syngenta Seeds, Syngenta brought suit against Delta Cotton for violating the Plant Variety Protection Act. We held that because Syngenta had the burden of showing that Delta Cotton had actual notice of its seeds' protected status, Delta Cotton did not waive its right to challenge the sufficiency of Syngenta's evidence on notice in a post-verdict motion for judgment as a matter of law. Id. at 1275-76. Here, in contrast, Ajinomoto was not challenging the sufficiency of GBT's evidence that Ajinomoto concealed the best mode as of the filing date of its Japanese application, but rather was raising an alternative theory of compliance with the best mode requirement for the first time after trial. Thus, the Commission did not abuse its discretion in finding the issue waived.

We thus affirm the Commission's final determination of no violation of section 337 based on the invalidity of asserted claim 15 of the '160 patent for failure to comply with the best mode requirement.

## II.

The Commission also found no violation of section 337 with regard to the '698 patent based on its finding that the patent is unenforceable due to inequitable conduct. Ajinomoto, however, did not challenge the Commission's finding of intent to deceive on

appeal, asserting only in a single sentence that the Commission's inequitable conduct decision must be reversed for relying on erroneous best mode conclusions. Such a conclusory assertion unaccompanied by developed argumentation does not preserve the issue for appeal. SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1319-20 (Fed. Cir. 2006). It is therefore waived here. But regardless, a decision not to address the Commission's inequitable conduct decision does not affect the finding of no violation of section 337 in this case given our holding that asserted claim 15 of the '698 patent is invalid for failure to comply with the best mode requirement. It also will not alter the outcome in other tribunals, where the Commission's decision has no binding effect. See Texas Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1569 (Fed. Cir. 1996).

#### CONCLUSION

For the foregoing reasons, we affirm the Commission's final determination of no violation of section 337.

AFFIRMED