

No. 2009-1081

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

AUG - 3 2009

JAN HORBALY
CLERK

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

**NONCONFIDENTIAL REPLY BRIEF OF
APPELLANTS AJINOMOTO CO., INC. and
AJINOMOTO HEARTLAND LLC**

JOSEPH M. MALKIN

ORRICK, HERRINGTON & SUTCLIFFE LLP

405 Howard Street
San Francisco, California 94105
(415) 773-5700

Attorneys for Appellants

AJINOMOTO CO., INC. and AJINOMOTO HEARTLAND LLC

August 3, 2009

(Additional counsel listed on reverse side.)

TABLE OF CONTENTS

	Page
INTRODUCTION	1
ARGUMENT.....	4
I. THE ITC AND GBT WRONGLY DEFINE THE “BEST MODE” REQUIREMENT IN TERMS OTHER THAN THE CLAIMED INVENTION.....	4
A. GBT and the ITC Propose Exceedingly Broad Rules for Disclosure Under the Best Mode Requirement.....	4
B. The GBT and ITC Positions Are Inconsistent With the Case Law.....	7
C. GBT’s and the ITC’s Other Attempts to Expand the Best Mode Requirement Fail	13
II. EVEN IF THE BEST MODE REQUIREMENT COULD BE BROADER THAN THE CLAIMED GENETIC MUTATIONS, THE COMMISSION ERRED IN FINDING VIOLATIONS OF THE BEST MODE REQUIREMENT FOR THE ’698 PATENT....	18
A. The ALJ Erred in Finding That Using Sucrose as a Nutrient and Using Sucrose Utilization Genes Was an Undisclosed Best Mode	19
1. The failure to disclose the use of sucrose and sucrose utilization genes cannot be a best mode violation because these technologies were known in the art	19
2. The use of sucrose and sucrose utilization genes is a production detail that need not be disclosed	22
B. The ALJ Erred in Finding That Dr. Kikuchi’s <i>lysC</i> Experiment Was an Undisclosed Best Mode	24
C. The ALJ Erred in Finding That Purportedly “Fictitious Data” in Table 1 Was a Best Mode Violation.....	26
D. The Inequitable Conduct Finding Must Be Reversed Because It Is Based on the Erroneous Best Mode Conclusions.....	28

TABLE OF CONTENTS
(continued)

	Page
III. THE COMMISSION ERRED WHEN IT INVALIDATED THE '160 PATENT BASED ON A PURPORTED BEST MODE VIOLATION IN THE JAPAN PRIORITY APPLICATION.....	29
CONCLUSION	33

CONFIDENTIAL MATERIAL OMITTED

Information regarding the receipt of the bacterial strain on pages 17-18 is designated as confidential by GBT and has been omitted.

TABLE OF AUTHORITIES

Page

FEDERAL CASES

<i>Ajinomoto, Inc. v. Archer-Daniels-Midland Co.</i> , 228 F.3d 1338 (Fed. Cir. 2000)	14, 17, 20
<i>Allvoice Computing PLC v. Nuance Commc 'ns, Inc.</i> , 504 F.3d 1236 (Fed. Cir. 2007)	8, 9, 13
<i>Amgen, Inc. v. Chugai Pharm. Co.</i> , 927 F.2d 1200 (Fed. Cir. 1991)	14, 15, 16
<i>Bayer AG v. Schein Pharm., Inc.</i> , 301 F.3d 1306 (Fed. Cir. 2002)	9, 10, 13, 17, 20
<i>Christianson v. Colt Indus. Operating Corp.</i> , 822 F.2d 1544 (Fed. Cir. 1987), <i>vacated on jurisdictional grounds</i> , 486 U.S. 800 (1988)	8, 9, 10, 11, 12
<i>Eli Lilly & Co. v. Barr Labs., Inc.</i> , 251 F.3d 955 (Fed. Cir. 2001)	9, 17
<i>Go Medical Indus. v. Inmed Corp.</i> , 471 F.3d 1264 (Fed. Cir. 2006)	29, 30
<i>Kaken Pharm. Co. v. ITC</i> , 1997 WL 152054, 111 F.3d 143 (Fed. Cir., March 31, 1997)	15
<i>Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Products Ltd.</i> , 559 F.3d 1317 (Fed. Cir. 2009)	28
<i>Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.</i> , 463 U.S. 29 (1982)	32
<i>Northern Telecom Ltd. v. Samsung Elecs. Co.</i> , 215 F.3d 1281 (Fed. Cir. 2000)	14

TABLE OF AUTHORITIES

(continued)

	Page
<i>Old Town Canoe Co. v. Confluence Holdings Corp.</i> , 448 F.3d 1309 (Fed. Cir. 2006)	28
<i>Randomex Inc. v. Scopus Corp.</i> , 849 F.2d 585 (Fed. Cir. 1988)	8
<i>SEC v. Chenery Corp.</i> , 332 U.S. 194 (1946)	33
<i>Syngenta Seeds, Inc. v. Delta Cotton Co-op., Inc.</i> , 457 F.3d 1269 (Fed. Cir. 2006)	31, 32
<i>Teleflex, Inc. v. Ficoso N. Am. Corp.</i> , 299 F.3d 1313 (Fed. Cir. 2002)	10, 20, 23, 24
<i>Zygo Corp. v. Wyko Corp.</i> , 79 F.3d 1563 (Fed. Cir. 1996)	8, 9, 12

MISCELLANEOUS

<i>Certain Salinomycin Biomass and Preparations Containing Same</i> , Inv. No. 337-TA-370, 1996 WL 1056309 (July 1996)	15
---	----

FEDERAL STATUTES

35 U.S.C. § 112 ¶ 1	<i>passim</i>
35 U.S.C. § 120	30, 31
35 U.S.C. § 251	30

INTRODUCTION

Neither GBT nor the ITC disputes that Ajinomoto's only inventions are specific genetic modifications to *E. coli*: (1) changes to one gene out of 4,000 (the '698 patent); and (2) changes to two nucleotides out of 4,000,000 (the '160 patent). Nor do they dispute that Ajinomoto disclosed the best ways of carrying out those claimed inventions: the right genes, the best modifications to those genes, and the best ways to incorporate those genetic modifications in bacteria. Similarly, neither disputes that Ajinomoto's patent rights are limited to those specific mutations. To design around these patents, one need make only two small genetic tweaks. No other change to the process of producing lysine with *E. coli* is necessary or would do.

The question, then, is whether the best mode requirement expands to encompass every host cell, cell discovery, and lysine production technology, simply because the claims recite not only the novel genetic modifications but the not-at-all novel process in which they are used. The ALJ believed it does, invalidating two patents that culminated years of work and millions of dollars of investment by Ajinomoto. All this based on the "failure" to disclose: (i) a laboratory strain Ajinomoto threw away shortly after the priority application; (ii) "sucrose" technology that was in the prior art; (iii) a

mutation experiment yielding random results; and (iv) a set of accurate data with no connection to carrying out the invention.

GBT and the ITC both defend the ALJ's result, but offer different articulations of the applicable rule. Neither is correct. GBT suggests the following: *a patent is invalid if there is a preferred and undisclosed technology relating in any way to any isolated claim term.* GBT's reasoning for requiring disclosure of sucrose utilization genes is illustrative: The phrase "liquid medium" appears in the claim; nutrients are one of the things that go into a "liquid medium"; a carbon source is one nutrient; sugars are one carbon source; sucrose is one sugar; sucrose utilization genes help process sucrose. The ITC does not adopt this "six-degrees-of-separation" reasoning. It reaches the same result, though, by urging a simple strict-liability test: *a patent is invalid if there is any undisclosed technology having anything to do with any preferred embodiment.* For example, Dr. Kikuchi's *lysC* experiment is a "best mode" because it was part of the genesis of laboratory strain WC80-196S (which the ITC calls a "preferred embodiment").

The implications for industry are staggering. Ajinomoto's opening brief discussed a hypothetical claim to a "car with a novel carburetor." Aji.

Br. 28-29. Any Ford patent for an automobile part with a claim mentioning a “car” would be imperiled because, under the ALJ’s rule, reciting the device or process in which the invention is used would require the disclosure of a library of “best” car technology, even if completely unrelated to the invention itself. GBT’s and the ITC’s arguments go even further. If they have their way, Ford would not only have to disclose its best “spoilers,” but its best technology *relating* to spoilers, and the best technology relating to that technology, and so on, until the patent bloats into an encyclopedia of all technology bearing any relation to cars or at least car speed – wildly out of proportion to the patent’s exclusionary right.

That cannot be correct. Everyone agrees the Ajinomoto inventors’ patents disclosed their inventions – the genetic modifications to the *ldc* and *dapA* genes. GBT does not want Ajinomoto’s undisclosed technologies – technologies that were worthless (AE-70), known (sucrose), or at best of historical interest (the *lysC* experiment). Rather, GBT wants to continue to import lysine produced in China using Ajinomoto’s stolen bacterial strain.

ARGUMENT

I. THE ITC AND GBT WRONGLY DEFINE THE “BEST MODE” REQUIREMENT IN TERMS OTHER THAN THE CLAIMED INVENTION.

A. GBT and the ITC Propose Exceedingly Broad Rules for Disclosure Under the Best Mode Requirement.

GBT. GBT urges the Court to adopt the following rule: a patent is invalid if the infringer can prove there is a preferred and undisclosed technology *relating in any way to any isolated claim term.*¹ Thus, GBT frames the “sucrose” best mode question as:

Did the Commission err in ruling that the inventors were required to disclose their best carbon source – the principal component of the “liquid medium” – for practicing this claim?

GBT Br. 1. “Liquid medium” is a hook into all Ajinomoto technology having anything to do with liquid media.

¹ GBT claims Ajinomoto “concedes that the asserted patents do not disclose the inventors’ best mode.” GBT Br. 34-35. Ajinomoto “conceded” no such thing. Ajinomoto simply made the tactical choice not to appeal the findings of fact regarding *state of mind* and to focus instead on the ALJ’s errors of law. Aji. Br. 41.

The breadth of GBT's proposition is evident the moment one considers the other technologies related to "liquid medium" described in the patent:

- a "carbon source," such as
 - "sugars"
 - "alcohols"
 - "organic acids"
- a "nitrogen source," such as
 - "inorganic ammonium salts"
 - "organic nitrogen"
 - "ammonia gas"
 - "aqueous ammonia"
- "required substances," such as "organic trace nutrients"
 - "vitamin B₁"
 - "L-isoleucine"
 - "yeast extract"
- organic ions, such as
 - "potassium phosphate"
 - "magnesium sulfate"
 - "iron ion"

A246, 251-52. GBT could have focused its "best mode" attack on any one of these. And that is just for the phrase "liquid medium." It snowballs from there. Take the claim term "microorganism," for example. GBT's rule would require Ajinomoto to disclose every preference relating to each of the 4,000 genes and 4,000,000 nucleotides in any "microorganism" used in Ajinomoto's lab.

The ITC. The ITC gets the same result in a different way – by starting with what it calls the “preferred embodiment” and expanding from there. The ITC proposes this two prong test: “the best mode requirement extends to [i] the *preferred embodiment* of claimed subject matter *or* [ii] subject matter that *materially affects* the best mode of the claimed invention [a preferred embodiment].” ITC Br. 33 (emphasis added).

The ITC’s first prong is a strict liability test – a patent is invalid for failure to disclose a preferred embodiment, without regard to whether those of skill in the art would gain anything from its disclosure. Ignore that it is undisputed that Ajinomoto’s inventors disclosed the publicly available host strain they started with (W3110), put its modified progeny on deposit (WC80-196), and fully disclosed altering that progeny with the patented *lde* mutation. A8346-48, 284, 287-88. In the ITC’s eyes, Ajinomoto failed the strict liability test because it needed to disclose the word “WC80-196S” – the laboratory name of what is disclosed as WC196 – supposedly the “best and only embodiment of the claimed invention.” ITC Br. 33.

The ITC’s second prong is another strict liability test – a patent is invalid for failure to disclose anything that “materially affects” the properties of a preferred embodiment. There is no need to determine how or

even whether “sucrose” or “Dr. Kikuchi’s *lysC* experiment” relate to “carrying out [the] invention.” 35 U.S.C. § 112 ¶ 1. They must be disclosed because they somehow “materially affect” the properties, not of carrying out the patented *ldc* mutation, but of the laboratory strain used to discover the *ldc* gene. *Id.* at 33. If Ford had a prototype “car with a novel carburetor,” it would have to disclose the preference for driving it with snow tires in the snow, using high-test spark plugs, etc. – all because these “materially affect” the properties of the car.

B. The GBT and ITC Positions Are Inconsistent With the Case Law.

The Patent Act requires only that “[t]he specification . . . shall set forth the best mode contemplated by the inventor *of carrying out his invention*,” 35 U.S.C. § 112 ¶ 1 (emphasis added) – not the best mode of achieving the broader objectives of the invention (the ALJ), not the best mode of enhancing every technology related to any isolated claim term (GBT), and not all technologies related to any preferred embodiment regardless of their relationship to “carrying out [the] invention” (the ITC).

The concept of novelty is central. That necessarily flows from the statutory language, which looks to the mode of “carrying out [the] invention.” 35 U.S.C. § 112 ¶ 1. That is why this Court has referred to

novelty in analyzing the best mode requirement. *See, e.g., Randomex Inc. v. Scopus Corp.*, 849 F.2d 585 (Fed. Cir. 1988). In *Randomex*, the “claimed invention [was] a portable machine for cleaning computer disk packs.” *Id.* at 588-89. The patentee deliberately withheld its best cleaning fluid. Even though cleaning fluid was integral to using the claimed invention, the cleaning fluid disclosure was adequate because “[t]his invention neither added nor claimed to add anything to the prior art respecting cleaning fluid.” *Id.* at 590 (emphasis added).

The concept of novelty is implicit in the cases that focus on what is novel and not on claim terms that may recite the apparatus or process in which the novel feature is used. *Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544 (Fed. Cir. 1987), *vacated on jurisdictional grounds*, 486 U.S. 800 (1988); *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563 (Fed. Cir. 1996); *Allvoice Computing PLC v. Nuance Commc'ns, Inc.*, 504 F.3d 1236 (Fed. Cir. 2007).

GBT and the ITC deny “novelty” has any role in the best mode determination. ITC Br. 32 n.25; *see* GBT Br. 44. GBT attacks a straw man – arguing Ajinomoto’s position is that the best mode determination *only* takes “novelty” into account. GBT Br. 44. That is not Ajinomoto’s

position. There is no bright-line rule, as this Court recognized in *Zygo*. See 79 F.3d at 1567. Identifying the “claimed invention,” and, therefore, the scope of the best mode disclosure requirement, changes from context to context. The considerations are different for a picture claim to a novel compound (e.g., *Bayer*), a “combination” claim composed of known elements from the prior art (e.g., *Allvoice*), or a claim to a novel technology that refers to the device or process in which it is used (e.g., *Christianson*).

The ITC believes the *Bayer* Court’s treatment of *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 965 (Fed. Cir. 2001), rejected Ajinomoto’s position. ITC Br. 32 n.25, citing *Bayer AG v. Schein Pharm., Inc.*, 301 F.3d 1306 (Fed. Cir. 2002). *Bayer*, however, did not address the interplay between “novelty” and the best mode requirement; the Court merely distinguished *Eli Lilly’s* treatment of best mode from its treatment of enablement. *Bayer*, 301 F.3d at 1323. Ironically, the ITC ignores what the *Bayer* Court had to say about *Eli Lilly* – “*Eli Lilly* thus applied the correct rule: unclaimed subject matter unrelated to the *properties of the invention* is not subject to the best mode disclosure requirement.” *Id.* (emphasis added).

The ITC also cites *Bayer* for the notion that every technology having a “material effect” on WC80-196S must be disclosed. ITC Br. 33. But the

ITC shears that phrase from its context. *Bayer* actually held: “Preferences that . . . relate to making or using the invention and have a material effect on the *properties of the claimed invention* must be disclosed.” 301 F.3d at 1321 (emphasis added). This is a far cry from pronouncing that *everything* having any “material effect” on *any* embodiment must be disclosed. The case law bears out the principle that a “material effect” is *an effect on what is inventive*.

Teleflex. The patent claimed a “remote control assembly” with over a dozen interrelated elements, one of which was a “clip.” *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1318 (Fed. Cir. 2002). Under the GBT or ITC rule, there would have been a best mode violation – and *Teleflex* should have been decided differently – because the undisclosed mode related to a claim term (a “clip”) and to *the* preferred (commercial) embodiment.

Christianson v. Colt. Under GBT’s rule, the patent to a novel part would be invalid, because the undisclosed mode related to the claim term “firearm.” The ITC’s test would reach the same result because the undisclosed mode related to *the* preferred embodiment, the M16.

GBT and the ITC dismiss *Christianson* by asserting “the undisclosed subject matter was not part of the claimed invention.” ITC Br. 33; GBT Br.

41; *cf.* Aji. Br. 31-33. They are right, but that undermines their arguments. In *Christianson*, the claims of one patent (U.S. Patent No. 3,977,296) were all limited to a “firearm” with novel features. 822 F.2d at 1547 n.1; Aji. Br. 31. In its “best mode” discussion, the *Christianson* court did not distinguish between the claims to the novel part alone and the claims to the novel part in a “firearm.” To the *Christianson* court, all were patents “on a single part.” The claimed invention was not a “firearm,” any more than Ajinomoto's claimed invention is a “bacterium” or a “liquid medium.”

GBT argues *Christianson* can be ignored as a “production detail” case. GBT Br. 42. Not so, but the important point is that this Court found it irrelevant that “firearm” appears in the claims. The claimed invention was not a *firearm*. “The ‘best mode’ for making and using the claimed parts relates to their use in *a* rifle, any rifle.” 822 F.2d at 1563 (emphasis in original). Similarly, as the ’160 patent made clear, “In the present invention, *any* bacterium belonging to the genus *Escherichia* is available for the use as a host” provided the disclosed mutations are introduced. A251 (emphasis

added). If, as GBT now contends, the firearm in *Christianson* is a “production detail,” then so is the host bacterium.²

Zygo v. Wyko. Under the GBT and ITC view, *Zygo* was wrongly decided. The undisclosed mode related to a claim term (“interferometer system”) and to *the* preferred embodiment (the patentee’s commercial interferometer system). GBT and the ITC dismiss *Zygo* with a single conclusory sentence: the claims in *Zygo* “simply do not require packaging of any sort,” 79 F.3d at 1567, while the Ajinomoto claims are different because they “require a bacterial strain and a culture medium.” GBT Br. 43; ITC Br. 47. But Ajinomoto’s claims do not “require” AE-70 (only an *Escherichia* or *E. coli*); sucrose or sucrose utilization genes (or even a sugar); a mutation experiment yielding random results; or the data in Table 1 – any more than the *Zygo* claims required packaging. True, the words “bacterium” and “culture medium” appear in the claims. But the term “system” appears in the *Zygo* patent, yet this Court did not find that to

² GBT derides Ajinomoto’s analysis of *Christianson* for “[r]elying upon an internet link” (the Web version of Patent No. 3,977,296). GBT Br. 41. The Web link merely provides easy access to the *language* of the claims-at-issue, which can also be found in the Patent Office and the appellate record in *Christianson*. Those claims were before the *Christianson* court, even if the opinion did not quote them.

require disclosure of the packaging in the patentee's best (commercial) system.

Allvoice v. Nuance. Under the GBT and ITC view, *Allvoice* would have been decided differently, because the undisclosed mode related to a claim term (a software “interface”) and to *the* preferred (commercial) embodiment. They treat *Allvoice* in the same conclusory terms: “The undisclosed material . . . related to a function that this Court specifically ruled was not encompassed by the claim.” GBT Br. 43; ITC Br. 32. That does not come to grips with the facts of the case or the claim language. The claim was to the software interface and updating the links was part of the patentee's commercial software interface that made it “better.” Just as the *Allvoice* court “specifically ruled [the undisclosed technology] was not encompassed by the claim,” so should this Court here.

Bayer v. Schein. Under the GBT or ITC rule, *Bayer* would have been decided differently as well – the undisclosed mode related to a claim term (the claimed compound) and to *every* embodiment.

C. GBT's and the ITC's Other Attempts to Expand the Best Mode Requirement Fail.

Extrinsic evidence. GBT suggests extrinsic evidence is relevant to determining the best mode. For example, GBT focuses on Ajinomoto

laboratory notebooks to show “host strains” were important to Ajinomoto’s commercial goals. GBT Br. 9. But it is an error of law to consult extrinsic evidence instead of the claimed invention to frame the “best mode” analysis. *See, e.g., Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1288 (Fed. Cir. 2000). In *Northern Telecom*, this Court reversed where the trial court framed the best mode inquiry by reference to internal company documents rather than the claimed invention. *Id.* at 1288-89.

Specification headers. GBT and the ITC suggest the best mode requirement expands to everything listed or discussed under the header “Best Mode For Carrying Out The Invention.” GBT Br. 10; ITC Br. 19. This header did not appear in either priority application because there is no “best mode” requirement in Japan. ⁸⁹⁸² ~~8968~~. There is no principle under which section headers have any bearing on defining the *scope* of the best mode analysis.

Special rules for biosynthesis. GBT promotes special rules for disclosing cells used in biosynthesis: “[T]hese cases all held or simply assumed that the patentees were required to disclose the cells used for biosynthesis.” GBT Br. 44 (citing *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991); *Ajinomoto, Inc. v. Archer-Daniels-Midland Co.*,

228 F.3d 1338 (Fed. Cir. 2000)).³ Contrary to GBT, these cases do not suggest a special rule for “cells.” Rather, each undermines GBT’s position.

In *Amgen*, the invention *was* cells. The claims were drawn to different kinds of cells, with at least one claim drawn to a “transfected CHO [Chinese hamster ovary] cell.” 927 F.2d at 1203-04. The infringer alleged the patentee violated the best mode requirement by failing to disclose its “best” CHO cells. *Id.* at 1209. The *Amgen* court held it adequate that the patentee disclosed *any* CHO cells, even though “the record shows that scientists were unable to duplicate Lin’s genetically-heterogeneous best mode cell strain.” *Id.* at 1210-12. “[W]e have long held that the issue is whether the disclosure is ‘adequate’ What is required is an adequate disclosure of the best mode, not a guarantee that every aspect of the specification be precisely and universally reproducible.” *Id.* at 1212. Here,

³ GBT also cites an ITC decision and its unpublished affirmance, *Certain Salinomycin Biomass and Preparations Containing Same*, Inv. No. 337-TA-370, 1996 WL 1056309 (July 1996), *aff’d sub nom. Kaken Pharm. Co. v. ITC*, 1997 WL 152054, 111 F.3d 143 (table) (Fed. Cir., March 31, 1997). There, the patentee would not have received the patent but for the undisclosed strain. The “inventors were well aware when they made their application for a patent and argued for patentability on the basis of ‘remarkably high yields’ . . . that those yields were not due solely to the medium but *dependent on which microorganism strain was cultured.*” *Salinomycin*, 1996 WL 1056309, at 47-48 (emphasis added).

the ALJ imposed the very strict liability regime this Court rejected in *Amgen* – requiring the disclosure AE-70 without considering that it was adequate that Ajinomoto disclosed other strains in the '160 patent.

In *Ajinomoto*, this Court rejected a “gotcha!” best mode challenge resembling those here. There, the invention *was* the production of a particular bacterium, with each claim directed to a “method for preparing” the bacterium. 228 F.3d at 1342. The infringer alleged Ajinomoto “hid” its use of the *relA+* gene, which could increase threonine production. *Id.* at 1346. This Court rejected that contention. Even though not disclosed in the patent, the *relA+* gene – like the sucrose technology here – was disclosed in the prior art. *Id.*

Misrepresentation. GBT addresses the “car with novel carburetor” hypothetical in a footnote. GBT Br. 38 n.5. While not responding to the hypothetical directly, GBT appears to suggest that the best mode requirement punishes any perceived wrongdoing, like inequitable conduct, but without the materiality limitation. *Id.* The best mode requirement, however, does not police the same beat as inequitable conduct. Either a

“mode” is subject to the disclosure requirement or it is not, without regard to any purported misrepresentation in the specification.⁴

* * * *

GBT and the ITC urge this Court to hold Ajinomoto was required to disclose an encyclopedia of lysine-production technology in exchange for exclusionary rights to two genetic mutations.⁵ This amounts to a call to overrule this Court’s holding that the best mode is a “two-way street,” where the patentee’s “best mode” obligations are no broader than his right to exclude. *Eli Lilly*, 251 F.3d at 967. For GBT and the ITC, every time a patentee adds a limitation to a claim – making the claim *narrower* – the “best mode” requirement becomes *broader*. Their version of the best mode requirement is limited only by a litigator’s ability to connect an undisclosed lab notebook entry to an isolated word in the claim, or an undisclosed

⁴ GBT attacks the hypothetical as “inapposite” because “these patents concern mutations to a living organism that is less predictable than a car engine.” GBT Br. 38, n.5. GBT appears to be conflating “enablement” with the “best mode” requirement. *Bayer*, 301 F.3d at 1322.

⁵ GBT designed around the patents by changing those two mutations. Aji. Br. 38-39. GBT does not deny this, but disputes that it can be found in the record. GBT Br. 37 n.4. To the contrary, GBT’s own Research Center Director []. A8928, 8963, 8977, 8980, 8972-77; see A481.

29 43 46

embodiment, rather than to what the patentee actually invented. The Court should reject those notions.

II. EVEN IF THE BEST MODE REQUIREMENT COULD BE BROADER THAN THE CLAIMED GENETIC MUTATIONS, THE COMMISSION ERRED IN FINDING VIOLATIONS OF THE BEST MODE REQUIREMENT FOR THE '698 PATENT.

The '698 patent invention is the specific genetic mutation and its use in a process to produce lysine. The claimed *ldc* gene mutation prevents lysine from decomposing, thereby increasing lysine production. The '698 patent does not claim to increase lysine production by any other means (such as the use of sucrose or the *lysC* mutation).

Ajinomoto's opening brief showed specific errors the ALJ made in finding the '698 patent invalid. Aji. Br. 39-56. Neither GBT nor the ITC disputes a single fact on which those arguments are based.⁶

⁶ GBT disagrees with one contextual fact, saying the strain was "purchased . . . from a government laboratory." GBT Br. 37 n.4. That is not what GBT's own Research Center Director said, however, testifying that another Chinese company [] A8963, 8929 8496-98. Also, genetic tests showed GBT's strain had multiple genetic modifications contained in Ajinomoto's strain that are not in the patents or literature – a sort of bacterial theft-detection tag. A8271, 8283, 8287-88.

A. The ALJ Erred in Finding That Using Sucrose as a Nutrient and Using Sucrose Utilization Genes Was an Undisclosed Best Mode.

1. The failure to disclose the use of sucrose and sucrose utilization genes cannot be a best mode violation because these technologies were known in the art.

Ajinomoto showed that, as a matter of law, sucrose and sucrose utilization genes cannot be “best modes” because the undisputed evidence is that:

- the use and potential benefits of sucrose and sucrose utilization genes were known in the art; and
- one of ordinary skill in the art would have known to use sucrose utilization genes if she wished to use sucrose as a nutrient, and how to do it.

Aji. Br. 40-45. These facts alone warrant reversing the ALJ.

The ITC does not contest these facts. GBT argues, “Ajinomoto has pointed to no record evidence that a person of skill in the art would know the benefits of using sucrose.” GBT Br. 47-48. To the contrary, Ajinomoto cited pages of that evidence, including the concessions of GBT’s expert. *See* Aji. Br. 40. GBT’s notes the ALJ found that “there is no disclosure *in the* ‘698 *patent* that would suggest . . . it is beneficial [to use sucrose].” GBT Br. 48 (citing A128-129) (emphasis added). That statement addresses only what is disclosed in the specification. GBT ignores the ALJ’s finding that

“the record supports Ajinomoto’s assertion regarding the knowledge of one of ordinary skill” in the art. A136.

GBT and the ITC both reject the rule of *Young Dental, Great Northern, Engel, Teleflex*, and *Ajinomoto* that one cannot “conceal” details known in the art. Aji. Br. 41-42; *cf.* GBT Br. 47-48; ITC Br. 38-40. This Court could not have been clearer – what is known need not be disclosed:

Requiring inclusion in the patent of known scientific/technological information would add an imprecise and open-ended criterion to the content of patent specifications. . . . A patent is not a scientific treatise, but a document that presumes a readership skilled in the field of the invention.

Ajinomoto, 228 F.3d at 1346-47.

GBT cites cases, such as *Bayer*, noting the *subjective* inquiry cannot be resolved by what was known in the art. GBT Br. 47. GBT leaves out the entire quote, however: “[W]hile the best mode requirement cannot be met solely by reference to the knowledge of one of skill in the art, neither does it demand disclosure of every preference an inventor possesses as of the filing date. As is always the case, the text of the statute provides the proper boundaries of the disclosure requirement.” *Bayer*, 301 F.3d at 1314-15.

Next, GBT cites evidence Ajinomoto ran tests quantifying results with different carbon sources. GBT Br. 48-49. But nobody contended below that

this sort of quantification of precise yields was subject to the best mode disclosure requirement. GBT bolds and italicizes a quote from a document claiming sucrose is superior, GBT Br. at 49 (citing A5159), but omits that the document referred to *threonine* (not lysine) production.

The ITC does not dispute the ALJ erred as a matter of law in finding he need only address state of mind regarding “sucrose” technology – and not the objective prong. Aji. Br. 42; *see* A136-37. GBT argues the “Commission devoted five pages of its decision to a consideration of the ‘objective’ prong.” GBT Br. 46, citing A126-130. Not a single sentence of those five pages, however, addresses the objective prong as applied to sucrose or sucrose utilization genes.

Finally, GBT and the ITC spend pages on the irrelevant Russian ’623 patent. GBT Br. 49-51; ITC Br. 41. Irrelevant, because the ALJ did not hold the *specific* genes used by Ajinomoto were subject to the best mode requirement. A127 (“Specifically, the patent fails to describe . . . adding sucrose utilization genes.”). Indeed, GBT and the ITC Staff were clear in their pre-hearing briefs that the purported best mode violation was the failure to disclose sucrose utilization genes in general. A1022-26; A1131-35. Although opaque, it appears the ALJ discussed the ’623 only to echo the

propriety of his holding regarding sucrose utilization genes in general. A128-29. Thus, the Court need not consider that the Russian inventors did not patent technology that unrelated Japanese inventors used 13 years earlier and that the Russians themselves identified as prior art.⁷

2. The use of sucrose and sucrose utilization genes is a production detail that need not be disclosed.

Ajinomoto showed that the choice of carbon sources – “glucose vs. sucrose” – is the quintessential production detail; the undisputed evidence shows that:

- lysine is not different or “better” when one uses sucrose rather than glucose;
- the choice to use glucose or sucrose in the production of lysine is made *solely* on considerations of cost and availability; and

⁷ The Japanese inventors used the specific sucrose PTS genes the Russian patent lists *as prior art*. Aji. Br. 44-45. GBT does not dispute that. Instead, GBT argues Ajinomoto expert Dr. Liao answered “yes ” to this compound question: whether “transposon *or* sucrose utilization genes” are the same. A21415 (emphasis added), *quoted at* GBT Br. 51. Although the genes came from a different strain, the *transposon* is the same, so his answer is correct, and not supportive of GBT’s claim. Aji. Br. 43. In the prosecution history, the Russians state, “[T]he claims do not encompass any sucrose PTS genes . . . but only those as isolated from the deposited strain VKPM B-7915.” Aji. Br. 44; A8800. The evidence is undisputed that Dr. Kikuchi used sucrose PTS genes from strain VKPM B-3996, not VKPM B-7915. Aji. Br. 43; A257, 4095, 4264, 4269, 4598.

- GBT itself uses glucose for its commercial production, as does Ajinomoto almost exclusively.

Aji. Br. 45-48. The header for GBT's Section VI(C)(2) suggests the ALJ found otherwise, referring to the "factual finding that the undisclosed use of sucrose and sucrose utilization genes were not mere 'production details.'"

GBT Br. 52. There was no such finding. The ALJ simply ignored Ajinomoto's evidence *and* its argument.

GBT and the ITC both argue sucrose cannot be a production detail because "the evidence suggests that using sucrose improves lysine yield." GBT Br. 52-53; *see* ITC Br. 46-47. The evidence not only suggests it – it was indisputably known and necessarily followed from the fact that sucrose has 5% more carbon atoms.⁸ A8339-40, 8254. Just because there is something about sucrose that can be said to make lysine production "better," however, does not make it any less a production detail.

Teleflex holds as much. The claims there were to a "motion transmitting remote control assembly," with "a clip manually insertable"; the undisclosed "clip" made the assembly better for its intended purpose. 299 F.3d at 1318-1319, 1329-1333; *see* Aji. Br. 45-48. Yet the *Teleflex* Court

⁸ Thus, sucrose potentially increases a hypothetical 20% yield to 21%.

found the technology outside the best mode requirement because the “claims do not mention any particular material, hardness, or material matching the clip.” 299 F.3d at 1332-33. GBT and the ITC do not dispute that this is true of “sucrose” as well – the claims “do not mention” any particular carbon source. True, the claims mention “liquid medium.” See ITC Br. 47. But that is a far more attenuated hook than in *Teleflex*, where “clip” was an express claim term. The *Teleflex* court held the undisclosed technologies were “not necessary to carry out the invention, but instead were dictated by customer requirements.” *Id.* The same is true of “sucrose.” In fact, for all its assertions about sucrose, GBT uses *only* glucose in its plant in China. Aji. Br. 47 n.6.

B. The ALJ Erred in Finding That Dr. Kikuchi’s *lysC* Experiment Was an Undisclosed Best Mode.

Ajinomoto showed the ALJ erred as a matter of law in invalidating Ajinomoto’s patent for failure to disclose Dr. Kikuchi’s *lysC* experiment.

Aji. Br. 48-54. This follows from the undisputed facts that:

- Dr. Kikuchi’s experiment was only a step in developing the host strain that Dr. Kikuchi *later* modified to contain the patented mutation;
- Dr. Kikuchi’s experiment produces random results;
- the results of Dr. Kikuchi’s experiment are on deposit;

- if there is any advantage to the *lysC* mutation, it was disclosed; and
- *the ALJ did not find that Dr. Kikuchi's experiment has or had any advantage when it comes to lysine production.*

Neither GBT's nor the ITC's brief contests any of these facts or any factual statement in Ajinomoto's Section II(B).⁹

Unclaimed subject matter. GBT and the ITC argue Dr. Kikuchi's experiment needed to be disclosed because it related to the creation of the "preferred embodiment," WC80-196S. GBT Br. 53-55; ITC Br. 38-41. But the "creation story" for an unclaimed (and disclosed) host strain is immaterial to carrying out the invention. In each case where a patentee has lost its patent, it was based on the intrinsic worth of an undisclosed technology, not the happenstance of its *relating* to a preferred embodiment. There is no case or principle supporting swapping out the requirement to "set forth the best mode contemplated by the inventor *of carrying out his invention,*" 35 U.S.C. § 112 ¶ 1, for a requirement to "set forth everything having to do with each preferred embodiment of the invention."

⁹ GBT argues Dr. Kikuchi's experiment was the "number one key thing done" to create the host strain in which Dr. Kikuchi later found the *ldc* gene. GBT Br. 2, 32, 55. The ALJ made no such finding. Even if he had, *finding* the patented gene cannot be a mode of "carrying out his invention." 35 U.S.C. § 112 ¶ 1.

Disclosed subject matter. GBT and the ITC agree the results of Dr. Kikuchi's *lysC* experiment are on deposit, the deposit is disclosed in the patent, and a deposit satisfies the best mode requirement. GBT Br. 55-58; ITC Br. 39-41. The problem they have with the deposit is that it is purportedly "misleading" because the patent does not disclose an accurate enough "creation story." Their argument makes no more sense than calling the deposit "misleading" for failing to disclose hundreds of other details that are part of the history of creating the deposited strain. The ALJ never found the "creation story" material to a mode of "carrying out [the] invention," 35 U.S.C. § 112 ¶ 1, or even material to lysine production generally. The rule GBT and the ITC urge would discourage inventors from ever describing a deposit again.

C. The ALJ Erred in Finding That Purportedly "Fictitious Data" in Table 1 Was a Best Mode Violation.

Ajinomoto showed the ALJ erred as a matter of law in invalidating Ajinomoto's patent for the purported "fictitious data" in Table 1. Aji. Br. 54-56. Nobody disputes that:

- the data is from *real* experiments; and
- the data is *accurate*.

Aji. Br. 54-56.¹⁰ The ALJ called this data “fictitious” because it was derived from strains with different internal designations at Ajinomoto, and because the specification does not indicate that two strains had sucrose utilization genes. Based on this, the ALJ found, two of the four Table 1 strains are “fictitious strains and that the data associated with them must therefore also be fictitious.” A141; *see* GBT Br. 58-59; ITC Br. 48-51. Since “sucrose utilization genes” are outside the best mode requirement, *supra* Sections I and II(B), it follows reporting accurate data is not a “best mode” violation for failure to mention that technology.

Moreover, the ALJ did not hold that the presence or absence of sucrose utilization genes had any relevance to the experiment reported on in Table 1. Table 1 contains “fictitious” data only in the sense that Marilyn Monroe’s movies were “fictitious” because the real star was named Norma Jeane Baker and she was a natural brunette. Just as *Some Like it Hot* is no less a movie because of the “fictitious” opening credits, the ’698 is no less a

¹⁰ GBT makes up one fact. GBT argues the data was generated using sucrose rather than glucose, based on little more than their say-so. GBT Br. 22; *cf.* A20667-80; 20754-57, 8335-36. GBT tried this argument below, A138, and the ALJ did not accept it. A140-41.

patent for Ajinomoto's having changed strain names – something having no bearing on the data in Table 1.

The ALJ erred by applying a strict liability test with no room for questions such as “how is this material to carrying out the invention?”

D. The Inequitable Conduct Finding Must Be Reversed Because It Is Based on the Erroneous Best Mode Conclusions.

Should this Court reverse even one of the purported best mode violations, it follows, as a matter of law, the Court should reverse the ALJ's inequitable conduct holding as well. Aji. Br. 56-57, *citing Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d 1309, 1322 (Fed. Cir. 2006). The ITC does not appear to disagree. ITC Br. 52-53. GBT argues, “Any one of the best mode violations is sufficient.” GBT Br. 60. This Court rejected that very reasoning in *Old Town* and again, more recently, in *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Products Ltd.*, 559 F.3d 1317, 1342 (Fed. Cir. 2009).

GBT claims “Ajinomoto has not contested” the fictitious data point and therefore inequitable conduct should stand. GBT Br. 60. The only way to make that statement true is to rip four pages out of Ajinomoto's brief (pages 54-57). The data in Table 1 is accurate. Even if it were not, the ALJ

only found Table 1 to be “material” to inequitable conduct by virtue of his best mode analysis. If his best mode analysis is in error, it follows that his materiality finding is erroneous as well.

III. THE COMMISSION ERRED WHEN IT INVALIDATED THE '160 PATENT BASED ON A PURPORTED BEST MODE VIOLATION IN THE JAPAN PRIORITY APPLICATION.

Ajinomoto showed that, even if the ALJ were correct that abandoned host strain AE-70 was an “undisclosed best mode” as of the 1993 Japanese priority application, the ALJ erred in equating this with invalidity of the '160 patent claim. Aji. Br. 57-60. The only result should be that the Japanese application is unavailable for priority purposes. *See* 35 U.S.C. § 120; *Go Medical Indus. v. Inmed Corp.*, 471 F.3d 1264 (Fed. Cir. 2006).

Section 120. GBT does not dispute that Section 120 provides for priority to *any* qualifying parent application. GBT Br. 61-64. The ITC tries to distinguish *Go Medical*, arguing the “Court did not reach the issue presented here” because the “parties stipulated that if the 1979 priority application lacked full disclosure of the best mode [then] the claims were invalid.” ITC Br. 59. Not quite correct: the patentee conceded a 1982 reference would anticipate “if [the patent] was not entitled to claim the filing date of its original 1979 application,” 471 F.3d at 1270, which only follows

because the “patent was issued from a 1985 continuation-in-part application that claimed the priority date [of 1979].” *Id.* at 1267. The concession does not negate the plain language of Section 120 or the *Go Medical* holding: the invention “was not [adequately] disclosed in the 1979 application . . . such that [the patentee] is not entitled to claim the priority date of *that* application.” *Id.* at 1272 (emphasis added).

The ITC interposes a number of policy arguments for sticking parties with an asserted priority date: the claim of priority is “set forth on the face of the patent and claimed in the prosecution history”; otherwise priority is a “moving target”; this is “analogous to a party that fails to set forth a patent claim”; this should be treated “analogously to claims for purposes of the reissue statute, 35 U.S.C. § 251.” ITC Br. 53-60. These arguments are not only wrong, they are irrelevant because there is a statute on point, one the ITC never takes head-on. Section 120 is worded conditionally: *if* the prior application satisfies Section 112, *then* a subsequent application can claim priority to it. Nothing in Section 120 even suggests the ITC’s “prove the date or lose the patent” rule. The ITC may call this a “moving target,” but it is not the patentee who moves it. The patentee claims a priority date. If the accused infringer chooses to attack that date, then – in light of the plain

words of Section 120 and *his* burden of proof – prevailing on that issue only results in the unavailability of the earlier priority date.

Waiver. Ajinomoto sought judgment on this issue in post-hearing briefing before the ALJ and on review before the ITC. A530-31, 845-47. This Court, under similar circumstances, found this does not constitute a waiver. *Syngenta Seeds, Inc. v. Delta Cotton Co-op., Inc.*, 457 F.3d 1269, 1276 (Fed. Cir. 2006).

The ITC tries to distinguish *Syngenta* on the facts. The ITC argues: “*Syngenta* is inapt inasmuch as a pre-hearing statement is not a pleading, and an administrative law judge is permitted to set deadlines for discovery and the presentation of issues for adjudication.” ITC Br. 55-56. It is unclear what the ITC means. The problem in *Syngenta* was not the purported failure to plead, but the purported failure to follow Federal Rule of Civil Procedure Rule 50(a)(2), which sets a deadline to state contentions in the same way as the ALJ’s Order No. 2. Neither relieves the opposing party of its burden of proof.

GBT argues that in *Syngenta* “the JMOL movant had attempted to raise the issue – the opposing party’s failure of proof – pre-verdict, but the trial court would not entertain the issue.” GBT Br. 62. There was no such

finding. In *Syngenta*, Delta Cotton had been found liable for infringement for selling bags of Syngenta-proprietary seed. The issue was whether Delta Cotton waived its argument that Syngenta failed to comply with the marking and notice provision of the Plant Variety Protection Act (“PVPA”). 457 F.3d at 1276. This Court held: “Delta Cotton did not waive its arguments based upon the knowledge requirements of § 2567, because Delta Cotton did not bear the burden of establishing the element of knowledge at trial.” 457 F.3d at 1276. The situation here is analogous: even if Ajinomoto did not state in its prehearing papers that “correct Section 120 law should apply,” Ajinomoto raised numerous “sufficiency of the evidence” contentions. A713-14, 737, 748-49.

GBT’s back-up argument is that there is another “best mode” issue at the later priority date, relating to strain TA-325. GBT Br. 63-64. GBT is wrong; the ALJ never found TA-325 was the best mode of practicing claim 15.¹¹ Thus, this issue is not appropriately before this Court. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 51 (1982) (“It is well established that an agency’s action must be upheld, if at all, on the basis

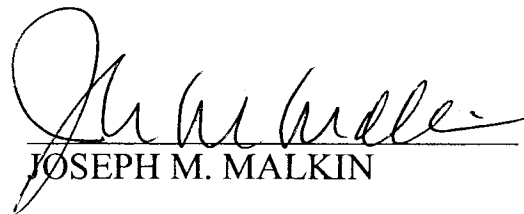
¹¹ As part of its inequitable conduct case, GBT alleged TA-325 was the “best mode” of claim 22. A109-113. The ALJ agreed with GBT, but the Commission granted review and took no position on this point. A277.

articulated by the agency itself.”); *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1946).

CONCLUSION

For the foregoing reasons, as well as those set forth in Ajinomoto’s opening brief, this Court should reverse the Commission’s decision, and remand to the Commission with directions to enter an exclusion order against GBT’s infringing lysine products.

Respectfully submitted,


JOSEPH M. MALKIN

August 3, 2009