UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

E.I. DU PONT DE NEMOURS AND COMPANY,
Petitioner,

v.

MONSANTO TECHNOLOGY LLC,
Patent Owner.

Case IPR2014-00333
Patent 7,832,143 B2


SNEDDEN, Administrative Patent Judge.

DECISION
Denying Institution of Inter Partes Review
37 C.F.R. § 42.108
I. INTRODUCTION


We have jurisdiction under 35 U.S.C. § 314. The standard for instituting an inter partes review is set forth in 35 U.S.C. § 314(a):

THRESHOLD – The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Upon consideration of the above-mentioned Petition and Preliminary Response, we conclude that DuPont has not established that there is a reasonable likelihood that it would prevail with respect to claims 1–11 of the ’143 patent. Accordingly, we decline to institute an inter partes review of those claims.

A. Related Proceedings

According to the parties, the ’143 patent is involved in the following co-pending case: Monsanto Company v. Pioneer Hi-Bred International, Inc., Case No. 4:12-cv-1090-CEJ (United States District Court for the Eastern District of Missouri). Pet. 4–5; Paper 7, 2.

In addition, concurrently with the instant Petition, DuPont also filed petitions for inter partes review for: claims 1-13 of U.S. Patent No. 8,071,845; claims 55, 58, 59, and 60 of U.S. Patent No. 8,028,469; claims 1, 2, 5-16, and 18-22 of U.S. Patent No. 8,245,439; and claims 1-26 of U.S. Patent No. 8,312,672. Pet. 2-3; Paper 7, 2; see IPR2014-00331, IPR2014-00332, IPR2014-00334, and
B. The ’143 patent (Ex. 1001)

The ’143 patent discloses plant breeding methods for “sampling transgenic seeds to test for the presence or absence of a transgene or the zygosity of a transgene (number of transgenes) in a population of seeds in a high throughput manner.” Ex. 1001, 5:59–63. The method is disclosed as generally comprising automatically removing a tissue sample from at least one or more seeds in a population of seeds, and depositing the removed tissue samples into individual compartments of a sample tray that holds a nucleic acid extraction buffer. Id. at 5:63 to 6:43. The nucleic acid is analyzed for the presence or absence of at least one genetic marker. Id. at 5:38–58.

The analysis does not affect the germination viability of the seeds. Id. at 5:7–16. Accordingly, seeds may be selected from the population based upon the results of the nucleic acid analysis, and plants may be subsequently cultivated from the selected seed. Id. Suitable seeds for use with the methods include wheat and maize seed. Id. at 6:47–66.

C. Independent Claim

Claim 1 is the only independent claim of the ’143 patent, and is reproduced below.

1. A high-throughput method for analyzing individual seeds in a population of seeds, the method comprising:
   removing a tissue sample from at least one or more seeds in a population of seeds while preserving germination viability of the at least one or more seeds from which the tissue sample is removed;
   depositing the tissue sample into an individual compartment of a sample tray;
   contacting the tissue sample with an extraction buffer to remove DNA from the tissue sample; and
   analyzing the extracted DNA for the presence or absence of a transgene of interest.
Claims 2–11 depend from claim 1, either directly or indirectly.

D. The Prior Art

DuPont relies on the following prior art.


DuPont further relies on a Declaration from Dr. Clifford F. Weil (Ex. 1010).
E. The Asserted Grounds

DuPont challenges the claims of the ’143 patent based on the following grounds:

<table>
<thead>
<tr>
<th>Challenged Claims</th>
<th>Basis</th>
<th>Reference[s]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 9</td>
<td>§ 102(b)</td>
<td>Sangtong</td>
</tr>
<tr>
<td>2–4, 8</td>
<td>§ 103(a)</td>
<td>Sangtong, Chunwongse</td>
</tr>
<tr>
<td>5, 6</td>
<td>§ 103(a)</td>
<td>Sangtong, He</td>
</tr>
<tr>
<td>7</td>
<td>§ 103(a)</td>
<td>Sangtong, He, Lipman</td>
</tr>
<tr>
<td>1, 9</td>
<td>§ 103(a)</td>
<td>Horigane 1, Sangtong</td>
</tr>
<tr>
<td>2–4, 8</td>
<td>§ 103(a)</td>
<td>Horigane 1, Sangtong, Chunwongse</td>
</tr>
<tr>
<td>5, 6</td>
<td>§ 103(a)</td>
<td>Horigane 1, Sangtong, He</td>
</tr>
<tr>
<td>7</td>
<td>§ 103(a)</td>
<td>Horigane 1, Sangtong, He, Lipman</td>
</tr>
<tr>
<td>10, 11</td>
<td>§ 103(a)</td>
<td>Horigane 1, Sangtong, Chunwongse, Horigane 2</td>
</tr>
</tbody>
</table>

II. ANALYSIS

A. Claim Interpretation

We interpret claims using the “broadest reasonable construction in light of the specification of the patent in which [they] appear[].” 37 C.F.R. § 42.100(b).

We presume that a claim term carries its “ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question” at the time of the invention. In re Translogic Tech., Inc., 504 F.3d 1249, 1257 (Fed. Cir. 2007). That presumption is rebutted, however, where the patentee acts as his own lexicographer, giving the term a particular meaning in the specification with “reasonable clarity, deliberateness, and precision.” In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We interpret the following terms of the challenged claims as part of our analysis. Our determination of whether to grant DuPont’s Petition does not require explicit construction of any other claim term at this time.
1. “High-throughput method for analyzing individual seeds in a population of seeds”

a. Whether the preamble of claim 1 is limiting

We first address whether the preamble of claim 1 is limiting. We recognize that, in general, “[a]n intended use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates.” Boehringer Ingelheim Vetmedica, Inc. v. Schering–Plough Corp., 320 F.3d 1339, 1345 (Fed. Cir. 2003). “But . . . preamble language will limit the claim if it recites not merely a context in which the invention may be used, but the essence of the invention without which performance of the recited steps is nothing but an academic exercise.” Id. (citing Griffin v. Bertina, 285 F.3d 1029, 1033 (Fed. Cir. 2002); see also, Pitney Bowes Inc. v. Hewlett Packard Co., 183 F.3d 1298, 1305 (Fed. Cir. 1999) (stating claim preamble is limiting when it is “necessary to give life, meaning, and vitality” to the claim). In Boehringer, for example, the Federal Circuit found the “growing and isolating . . . virus” language of a preamble limiting because “‘growing’ and ‘isolating’ are not merely circumstances in which the method may be useful, but instead are the raison d’être of the claimed method itself.” Boehringer, 320 F.3d at 1344–45. Without the preamble, the court found that “the claimed method [was] reduce[d] to nothing more than a process for producing cytopathic effects in sheets of cultured MA–104 cells—a process whose absence of fathomable utility rather suggests the academic exercise.” Id. at 1345. The court thus recognized that one of ordinary skill in the art would not understand the utility of the process without construing the “growing” and “isolating” language of the preamble as limiting.

We conclude that, as in Boehringer, one of ordinary skill in the art would not understand the utility of the process of claim 1, viewed in light of the specification, without construing the preamble language of the claim as limiting.
The body of claim 1 lacks any clear language indicating that the utility of the invention is for the analysis of individual seeds. Further, there are no steps in the claimed method that describes the “high-throughput” purpose of the preamble. Hence, the body of the claim does not set forth the essence of the invention, and we construe the preamble as limiting.

b. Interpretation of “high-throughput method”

As to the interpretation of “high-throughput method” recited in the preamble of claim 1, the dispute between the parties centers on the amount of automated technology that is required by the broadest reasonable construction of “high-throughput method,” viewed in light of the specification. DuPont asks that we construe the phrase “high-throughput method for analyzing individual seeds in a population of seeds” to mean “a method that enables analysis of a larger number of seeds in a population of seeds per unit time than does a completely manual method.” Pet. 7, citing Ex. 1001, 4:32–36; Ex. 1010 ¶ 52. Although DuPont (Pet. 7) and Dr. Weil (Ex. 1010, ¶ 52) acknowledge that the ’143 patent does not define the phrase “high-throughput method for analyzing individual seeds in a population of seeds,” DuPont, nonetheless, relies on the following passage from the specification to support this interpretation of the preamble phrase.

As a result, the marker-assisted breeding program results in a “high-throughput” and more efficient platform wherein a population of seeds having a desired trait, marker or genotype can be more effectively bulked in a shorter period of time, with less field and labor resources required.

Ex. 1001, 4:32–36.

Monsanto, on the other hand, contends that the broadest reasonable construction of the preamble phrase “high-throughput method,” viewed in light of the specification, is “a method that permits one to analyze a high volume of individual seeds quickly using automated technology.” Prelim. Resp. 21.
Monsanto directs our attention to several passages in the written description of the ’143 patent that describes “high-throughput” processes in such terms as “automatically,” “automated,” “automation,” and “robotics.” Id. at 21–24, citing Ex. 1001, 5:59 to 6:2, 6:28–31, 6:38–43, 6:44–46, 17:51–59. Monsanto also notes that the Oxford Dictionary of Biochemistry defines “high-throughput” as “a process that is scaled up, usually via increased levels of automation using robots.” Id. at 24, citing Ex. 2007.

We recognize that there is sometimes “a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.” Comark Commc’ns v. Harris Corp., 156 F.3d 1182, 1187 (Fed.Cir.1998) (citations omitted); see also Constant v. Advanced Micro–Devices, Inc., 848 F.2d 1560, 1571 (Fed.Cir.1988) (“Although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.”). We also recognize, however, that the specification contains a written description that “can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format.” SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1344 (Fed. Cir. 2001); cf. Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d 985, 991 (Fed. Cir. 1999) (“Varied use of a disputed term in the written description demonstrates the breadth of the term rather than providing a limited definition.”).

In this case, there is no special definition or other language in the specification that explicitly informs us as to the meaning of “high-throughput” to one of skill in the art. We are, however, persuaded by Monsanto’s evidence and reasoning that the ordinary meaning of the term “high-throughput” typically
implies automation, such as with the use of robots, and that the term “high-throughput” is used throughout the written description of the ’143 patent in a manner consistent with an interpretation that includes automation. Accordingly, we construe the phrase “high-throughput method” to mean “a process that is scaled up via increased levels of automation.” Our construction of the term “high-throughput method” is based on the definition of that term set forth in the Oxford Dictionary of Biochemistry, but we have modified that definition such that our interpretation requires automation, as opposed to an interpretation that “usually” includes automation. This construction is supported by the specification of the ’143 patent, which consistently uses the term “high-throughput” in the context of automated methods.

B. Asserted Grounds of Unpatentability

1. Anticipation of Claims 1 and 9 by Sangtong (Ex. 1003)

DuPont contends that claims 1 and 9 are anticipated by Sangtong. Pet. 15–21. DuPont relies on the following disclosures of Sangtong. Sangtong discloses a method for the detection of transgenes and their protein products in the endosperm of individual maize kernels. Ex. 1003, 151–152. Tissue is removed from maize kernels such that the embryo is not damaged, and the kernels can be germinated subsequently. Id. DNA is then extracted from the tissue and analyzed for the presence or absence of a transgene of interest. Id. at 154. Sangtong further discloses that “[a]ll liquid handling steps are carried out in 96-well format, which lends itself to automation for high-throughput.” Id. at 152.

DuPont concludes that Sangtong discloses a high-throughput method of analyzing individual seeds because Sangtong discloses using 96-well sample trays

---

1 Claim 9 depends from claim 1 and recites that the population of seeds of claim 1 may be maize seed.
for extracting DNA from many samples at a time. Pet. 18–19. We are not persuaded. Anticipation requires that every element of the claimed invention must be found in a single prior art reference, arranged as in the claim. Brown v. 3M, 265 F.3d 1349, 1351 (Fed. Cir. 2001). In that regard, Sangtong does not disclose a high-throughput method utilizing automation. Rather, Sangtong merely discloses a method that may be adapted to automation, not a method scaled up via increased levels of automation. Accordingly, Sangtong fails to teach every element of the claim. DuPont, therefore, has not demonstrated a reasonable likelihood that Sangtong anticipates claims 1 and 9 of the ’143 patent.

2. Obviousness of Claims 2–8 Over the Combination of Sangtong, Chunwongse, He, and Lipman

Each of claims 2–8 depends from claim 1, either directly or indirectly. DuPont contends that claims 2–8 are obvious over the combination of Sangtong, Chunwongse, He, and Lipman. Pet. 21–32. With respect to claims 2-8, DuPont relies on its analysis of claim 1 as anticipated by Sangtong to show that the elements of claim 1 are taught by the combination. Id. at 22. As explained above, however, Sangtong does not disclose a high-throughput method utilizing automation, and thus fails to teach every element of claim 1. DuPont points to no disclosure in any of Chunwongse, He, and Lipman that provides the missing element for claim 1. Furthermore, DuPont does not present any articulated reasoning with rational underpinning to support a conclusion of obviousness. See KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007). For example, DuPont does not explain why a person of ordinary skill in the art would have modified the teachings of Sangtong to arrive at the limitations of claim 1, as required by dependent claims 2-8. Further, DuPont does not explain sufficiently how the disclosures of Chunwongse, He, and/or Lipman cure the deficiency of Sangtong. Accordingly, upon review of DuPont’s analysis of the evidence of record, DuPont
has not set forth sufficiently how each element of claims 2-8 is taught or suggested by Sangtong, alone or in combination with Chunwongse, He and Lipman.

We are not persuaded, therefore, that there is a reasonable likelihood that DuPont would prevail at trial based on obviousness of any of claims 2–8 over the combination of Sangtong, Chunwongse, He, and Lipman.

3. Obviousness of Claims 1 and 9 Over the Combination of Horigane 1 and Sangtong

DuPont contends that claims 1 and 9 would have been obvious over the combination of Horigane 1 and Sangtong. Pet. 34–41. Horigane 1 discloses a system for analyzing plant tissue samples by molecular spectrometry for the purposes of improving plant breeds, biometrics authentication, and quality evaluation. Ex. 1009, 398. A kernel holder capable of holding multiple wheat grains is used to keep the kernel at the desired angle and height. Id. at 399. Analytical samples of wheat grains are cut with a cutting device to prepare an analytical surface. Id. at 400. Horigane 1 discloses that the cutting device “is programmed for cutting and grinding with a sequential controller and can repeatedly be used for the preparation of analytical surface under the same conditions, and therefore polyspecimen samples to be analyzed can be prepared with high reproducibility.” Id. Embryo portions are also removed by cutting and can be subsequently germinated. Id.

DuPont acknowledges that Horigane 1 does not disclose the steps of depositing the tissue sample into an individual compartment of a sample tray, contacting the tissue sample with an extraction buffer to remove DNA from the tissue sample, or analyzing the extracted DNA for the presence or absence of a transgene of interest as required by claim 1. Pet. 40. DuPont relies on Sangtong for the disclosure of the claimed elements absent in Horigane 1. Id. Sangtong discloses a method for the detection of transgenes and their protein products in the
endosperm of individual maize kernels. Ex. 1003, 151–152. Tissue is removed from maize kernels such that the embryo is not damaged and the kernels can be subsequently germinated. *Id.* DNA is then extracted from the tissue and analyzed for the presence or absence of a transgene of interest. *Id.* at 154. DNA extraction is performed using a 96-well format (individual compartment). *Id.* at 152.

DuPont contends that both Sangtong and Horigane 1 relate to methods for sampling seeds, while preserving germination viability, and analyzing the sampled tissue for a given trait. Pet. 13–14. DuPont asserts that a person of ordinary skill in the art would have been motivated to combine the disclosures of Horigane 1 and Sangtong due to the ongoing desire to increase the efficiency and volume of seed analysis methods. In this regard, DuPont notes that Sangtong describes a high-throughput DNA extraction method using a 96-well sample tray format suitable for automation, and Horigane 1 describes a high-throughput seed sampling method using a computer-controlled blade cutting device for sampling a population of seeds. *Id.*

Upon review of DuPont’s analysis and the evidence of record, summarized above, we are not persuaded that DuPont has set forth sufficiently how Horigane 1 and Sangtong may be combined to arrive at the methods of claims 1 and 9. For example, DuPont does not provide an adequate rationale for why a person of ordinary skill in the art would modify Horigane 1 for tissue collection used in DNA analysis. Horigane 1 appears to grind multiple seeds at a time for the purposes of making a reproducible analytical surface for study using spectrometric analytical techniques. Ex. 1009, Figure 3B, lower left. In Horigane 1, the tissue removed from the seeds by grinding is not analyzed; it is the remaining analytical surface of the seed that is analyzed. In Santong, however, it is the ground material that is analyzed. Sangtong carefully cleans the grinding equipment between the
grinding of seeds to prevent cross-contamination of the ground material from the seed that is to be tested. Ex. 1003, 153. DuPont contends that the ordinary artisan would have used the method of Horrigane I and analyzed the sampled seed for the presence or absence of a transgene. Pet. 27. What is missing from DuPont’s challenge, however, is an explanation of how the ordinary artisan would have modified the method of Horrigane I, wherein multiple seeds are ground simultaneously, to prevent cross-contamination of protein and DNA between the seeds, as required by the method disclosed by Sangtong. See KSR Int’l Co., 550 U.S. at 418 (reaffirming that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (quoting In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006)). Accordingly, we conclude that DuPont has not demonstrated that there is a reasonable likelihood that it would prevail in showing that claims 1 and 9 of the ’143 patent would have been obvious over the combination of Horrigane 1 and Sangtong.

4. Obviousness of Claims 2–8 Over the Combination of Horrigane 1, Sangtong, Chunwongse, He, and Lipman

DuPont contends that claims 2–8 are obvious over the combination of Horrigane 1, Sangtong, Chunwongse, He, and Lipman. Pet. 41–52. As explained above, however, we are not persuaded that DuPont has set forth sufficiently how Horrigane 1 and Sangtong may be combined to arrive at the methods of claim 1, from which claims 2–8 depend. DuPont points to no other disclosure in any of Chunwongse, He, and Lipman and provides no further rationale to cure this deficiency. Accordingly, upon review of DuPont’s analysis of the evidence of record, we are not persuaded that there is a reasonable likelihood that DuPont
would prevail at trial based on obviousness of any one of claims 2–8 over the combination of Horigane 1, Horigane 2, Keller, Kelly, and CN2510248.

C. Obviousness of Claims 10 and 11 Over the Combination of Horigane 1, Sangtong, Horigane 2, and Chunwongse

DuPont contends that claims 10 and 11 would have been obvious over the combination of Horigane 1, Sangtong, Horigane 2, and Chunwongse. Pet. 52–59. Claims 10 and 11 depend from claim 1 and provide as follows:

10. The method as set forth in claim 1, wherein removing the tissue sample from at least one or more seeds in a population of seeds and depositing the tissue sample into an individual compartment of a sample tray are done by an automated seed sampler system.

11. The method of claim 1, further comprising removing a tissue sample from each seed in a population of seeds and depositing each tissue sample into an individual compartment of a sample tray having an extraction buffer present therein using an automated system; and analyzing the extracted DNA from each tissue sample for the presence or absence of a transgene of interest.

As in previous grounds discussed above, DuPont relies upon Horigane 1 and Sangtong for the elements of claim 1. Briefly, Sangtong is relied upon for the extraction and analysis of tissue sample DNA for the presence or absence of a transgene of interest. Horigane 1 is relied upon for the disclosure of a system for analyzing plant tissue samples by molecular spectrometry. Ex. 1009, 398. In Horigane 1, wheat grains are placed in a kernel holder capable of holding multiple wheat grains at a desired angle and height. Id. at 399. Wheat grains are then cut with a computer-controlled cutting device to make an analytical surface. Id. at 400. The processed wheat grains are then analyzed using spectroscopy. Id.

DuPont acknowledges that Horigane 1 is silent regarding depositing a tissue sample into a sample tray via an automated system. Pet. 56. For this element of claim 10, DuPont relies on Horigane 2. Id. at 56–57. Horigane 2 discloses an
apparatus for settling, analyzing, and sorting materials. Ex. 1004, abstract, ¶¶ 54–83. Seeds, for example, are settled into a holder at a definite posture and held in place using a light-hardenable adhesive. *Id.* ¶ 56. Once arranged in the holder, each individual seed may be cut or ground to prepare an analyzing surface. *Id.* ¶ 69. After the seeds are analyzed, the seed holders are transferred to a computer-controlled sorting device in which desirable seeds are pushed from the holder and into a collector means. *Id.* ¶¶ 99-100.

DuPont contends that one of ordinary skill in the art would have been motivated to combine Horigane 1, Sangtong, and Horigane 2, because all of these publications describe a high-throughput method for sampling seed and because all publications disclose extracting the seed sample in such a way as to preserve the seed’s germination viability. Pet. 57.

Upon review of DuPont’s analysis and the evidence of record, summarized above, we are not persuaded that DuPont has set forth sufficiently how each element of claim 10 of the ’143 patent is taught or suggested by the combination of Horigane 1, Sangtong, and Horigane 2. Claim 10 requires the automatic removal of a tissue sample and the automatic depositing of that tissue sample into an individual compartment of a sample tray. Horigane 2, relied upon by DuPont for the elements of claims 10, does not disclose the automatic removal and depositing of a tissue sample. Rather, the apparatus of Horigane 2 is designed to place a seed in a holder where tissue is then removed from the seed, not for collection, but for the purposes of preparing an analytical surface on the seed. Ex. 1004, abstract, ¶¶ 54–83. Accordingly, we are not persuaded that the prior art references relied upon by DuPont disclose each element of claim 10.

Furthermore, DuPont does not explain adequately why a person of ordinary skill in the art would have modified the automated systems Horigane 1 and
Horigane 2, designed for spectroscopic analysis, with the DNA analytical method of Sangtong. The rationale that each of Horigane 1, Sangtong, and Horigane 2 relate to high-throughput methods for sampling seeds in a manner that preserves the seed’s ability to germinate does not explain how a person of ordinary skill in the art would have modified the prior art systems to arrive at the invention described in claim 10.

Like claim 10, claim 11 requires the automatic removal of a tissue sample and the automatic depositing of that tissue sample into an individual compartment of a sample tray. Chunwongse is not relied upon by DuPont to cure the deficiency of the combination of Horigane 1, Sangtong, and Horigane 2. Pet. 58–59. Accordingly, we are not persuaded that the prior art references relied upon by DuPont disclose each element of claim 11 for the reasons discussed above.

In view of the above, we are not persuaded that there is a reasonable likelihood that DuPont would prevail at trial with respect to claims 10 and 11 of the ’143 patent, based on obviousness of claims 10 and 11 over the combination of Horigane 1, Sangtong, and Horigane 2.

D. Conclusion

The Petition does not persuade us that there is a reasonable likelihood that at least one of the challenged claims is unpatentable based on the asserted grounds. We do not institute an inter partes review on claims 1–11 of the ’143 patent for the reasons stated above.

III. ORDER

In consideration of the foregoing, it is hereby ORDERED that the petition challenging the patentability of claims 1-30 of U.S. Patent No. 7,832,143 B2 is denied as to all challenged claims and no trial is instituted.
IPR2014-00333
Patent 7,832,143 B2

For PETITIONER:

Todd R. Walters
Erin M. Dunston
BUCHANAN INGERSOLL & ROONEY PC
todd.walters@bipc.com
erin.dunston@bipc.com

For PATENT OWNER:

Andrew Sommer
Melinda Patterson
WINSTON & STRAWN LLP
asommer@winston.com
mpatterson@winston.com