Paper 33 Date: August 31, 2021

# UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD \_\_\_\_\_\_

SYNGENTA CROP PROTECTION AG, Petitioner,

v.

FMC CORPORATION, Patent Owner.

PGR2020-00028 Patent 10,294,202 B2

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

HARDMAN, Administrative Patent Judge.

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
35 U.S.C. § 328(a)
Denying Petitioner's Motions to Exclude
37 C.F.R. § 42.64

## I. INTRODUCTION

This is a Final Written Decision in a post grant review challenging the patentability of claims 1–7, 9–13, and 21–31 of U.S. Patent No. 10,294,202 B2 ("the '202 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 326(e) (2018). Having reviewed the parties' arguments and supporting evidence, for the reasons discussed below, we find that Petitioner has demonstrated by a preponderance of the evidence that claims 1–3, 9–13, and 21–30 are unpatentable, but has not demonstrated by a preponderance of the evidence that claims 4–7 and 31 are unpatentable. We also deny Petitioner's motions to exclude.

## A. Procedural History

Syngenta Crop Protection AG ("Petitioner") filed a Petition requesting post-grant review of claims 1–7, 9–13, and 21–31 of the '202 patent. Paper 1 ("Pet."). FMC Corporation ("Patent Owner") filed a Preliminary Response. Paper 7. Based on the Petition and Preliminary Response, we determined that Petitioner more likely than not would prevail in showing that at least one of the challenged claims was unpatentable. Thus, we instituted trial. Paper 8 ("Inst. Dec.").

After institution, Patent Owner filed a Response (Paper 15, "Resp."), Petitioner filed a Reply (Paper 19, "Reply"), and Patent Owner filed a Surreply (Paper 20, "Sur-reply"). On June 16, 2021, we held an oral hearing, the transcript of which is of record. Paper 32 ("Tr.").

Petitioner filed a motion to exclude certain opinions of Patent Owner's expert Dr. Dayan (Paper 24), Patent Owner filed an opposition (Paper 27), and Petitioner filed a reply (Paper 28).

Petitioner also filed a motion to exclude testimony, exhibits, and arguments regarding patents issued to its expert Dr. Hunt (Paper 25), Patent Owner filed an opposition (Paper 26), and Petitioner filed a reply (Paper 29).

## B. Real Parties in Interest

Petitioner identifies the real parties in interest as Syngenta Crop Protection AG and Syngenta AG.<sup>1</sup> Paper 11, 1. Patent Owner identifies itself as the real party in interest. Paper 3, 2.

#### C. Related Matters

Petitioner identifies two applications to which the '202 patent claims priority: (1) U.S. Provisional Application No. 61/911,324 (filed 12/3/2013); and (2) PCT/US2014/068073, WO2015/084796 (published June 11, 2015). Pet. 3–4.

Patent Owner states that it "knows of no judicial or administrative matters that may affect or be affected by a decision in this proceeding." Paper 3, 2.

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<sup>&</sup>lt;sup>1</sup> In its Preliminary Response, Patent Owner argued that the Petition "fails to name all real parties in interest." Paper 7, 2, 61. We authorized Patent Owner to file a brief addressing real parties in interest (Paper 10, 3), but Patent Owner elected not to do so, stating: "In the interest of expediting the proceeding, FMC declined to pursue the issue further. However, FMC does not concede that the petition does, in fact, name all real parties in interest." Resp. 4 n.4. Because Patent Owner has not raised a real party in interest argument during the trial, it is waived. *See In re NuVasive*, 842 F.3d 1376, 1380–81 (Fed. Cir. 2016) (finding that an argument raised in preliminary proceedings but not raised during trial is waived).

#### D. The '202 Patent

The '202 patent, titled "Pyrrolidinones as Herbicides," "relates to certain pyrrolidinones, their N-oxides and salts, and compositions and methods of their use for controlling undesirable vegetation." Ex. 1001, code (54), 1:5–7. The Specification states that "[t]he control of undesired vegetation is extremely important in achieving high crop efficiency," and that "[m]any products are commercially available for these purposes, but the need continues for new compounds that are more effective, less costly, less toxic, environmentally safer or have different sites of action." *Id.* at 1:11–23.

The '202 patent provides sixteen compound synthesis schemes (*id.* at 33:9–41:49) and seven example syntheses (*id.* at 42:44–50:35). The '202 patent also discloses approximately 350 compounds that were synthesized (Index Tables A–D), 335 of which were tested for herbicidal effect on various crop and weed species (Tables A–H5). *Id.* at 173:49–54, 174:1–182:50, 182:57–285:27.

#### E. Illustrative Claim

Of the challenged claims, claims 1 and 31 are independent. Claim 1, reproduced below, is illustrative:

1. A compound selected from Formula I, N-oxides and salts thereof:

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#### wherein

- Q¹ is a phenyl ring optionally substituted with up to 5 substituents independently selected from R³; or a 5- to 6-membered heterocyclic ring or an 8- to 10-membered heteroaromatic bicyclic ring system, each ring or ring system containing ring members selected from carbon atoms and 1 to 4 heteroatoms independently selected from up to 2 O, up to 2 S and up to 4 N atoms, wherein up to 3 carbon ring members are independently selected from C(=O) and C(=S), and the sulfur atom ring members are independently selected from S(=O)<sub>u</sub>(=NR<sup>8</sup>)<sub>v</sub>, each ring or ring system optionally substituted with up to 5 substituents independently selected from R³ on carbon atom ring members and selected from R³ on nitrogen atom ring members;
- Q² is a phenyl ring or a naphthalenyl ring system, each ring or ring system optionally substituted with up to 5 substituents independently selected from R¹0; or a 5- to 6-membered fully unsaturated heterocyclic ring or an 8- to 10-membered heteroaromatic bicyclic ring system, each ring or ring system containing ring members selected from carbon atoms and 1 to 4 heteroatoms independently selected from up to 2 O, up to 2 S and up to 4 N atoms, wherein up to 3 carbon ring members are independently selected from C(=O) and C(=S), and the sulfur atom ring members are independently selected from S(=O)u(=NR²)v, each ring or ring system optionally substituted with up to 5 substituents independently selected from R¹¹ on carbon atom ring members and selected from R¹¹ on nitrogen atom ring members;

Y<sup>1</sup> and Y<sup>2</sup> are each independently O, S or NR<sup>12</sup>;

R<sup>1</sup> is H, hydroxy, amino, C<sub>1</sub>-C<sub>6</sub> alkyl, C<sub>1</sub>-C<sub>6</sub> haloalkyl, C<sub>2</sub>-C<sub>6</sub> alkenyl, C<sub>3</sub>-C<sub>6</sub> alkynyl, C<sub>4</sub>-C<sub>8</sub> cycloalkylalkyl, C<sub>2</sub>-C<sub>8</sub> alkoxyalkyl, C<sub>2</sub>-C<sub>8</sub> haloalkoxyalkyl, C<sub>2</sub>-C<sub>8</sub> alkylsulfinylalkyl, C<sub>2</sub>-C<sub>8</sub> alkylsulfonylalkyl, C<sub>2</sub>-C<sub>8</sub> alkylcarbonyl, C<sub>2</sub>-C<sub>8</sub> haloalkylcarbonyl, C<sub>4</sub>-C<sub>10</sub> cycloalkylcarbonyl, C<sub>2</sub>-C<sub>8</sub> haloalkoxycarbonyl, C<sub>2</sub>-C<sub>8</sub> haloalkoxycarbonyl, C<sub>4</sub>-C<sub>10</sub> cycloalkoxycarbonyl, C<sub>2</sub>-C<sub>8</sub> alkylaminocarbonyl, C<sub>3</sub>-C<sub>10</sub> dialkylaminocarbonyl, C<sub>4</sub>-

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C<sub>10</sub> cycloalkylaminocarbonyl, C<sub>1</sub>-C<sub>6</sub> alkoxy, C<sub>1</sub>-C<sub>6</sub> alkylthio, C<sub>1</sub>-C<sub>6</sub> haloalkylthio, C<sub>3</sub>-C<sub>8</sub> cycloalkylthio, C<sub>1</sub>-C<sub>6</sub> alkylsulfinyl, C<sub>1</sub>-C<sub>6</sub> haloalkylsulfinyl, C<sub>3</sub>-C<sub>8</sub> cycloalkylsulfinyl, C<sub>1</sub>-C<sub>6</sub> alkylsulfonyl, C<sub>1</sub>-C<sub>6</sub> haloalkylsulfonyl, C<sub>3</sub>-C<sub>8</sub> cycloalkylsulfonyl, C<sub>1</sub>-C<sub>6</sub> alkylaminosulfonyl, C<sub>2</sub>-C<sub>8</sub> dialkylaminosulfonyl, C<sub>3</sub>-C<sub>10</sub> trialkylsilyl or G<sup>1</sup>; R<sup>2</sup> and R<sup>3</sup> are each independently H, halogen or C<sub>1</sub>-C<sub>4</sub> alkyl; or R<sup>2</sup> and R<sup>3</sup> are taken together with the carbon atom to which they are bonded to form a C<sub>3</sub>-C<sub>7</sub> cycloalkyl ring; R<sup>4</sup> and R<sup>5</sup> are each independently H, halogen or C<sub>1</sub>-C<sub>4</sub> alkyl; R<sup>6</sup> is H, hydroxy, amino, C<sub>1</sub>-C<sub>6</sub> alkyl, C<sub>1</sub>-C<sub>6</sub> haloalkyl, C<sub>2</sub>-C<sub>6</sub> alkenyl, C<sub>3</sub>-C<sub>6</sub> alkynyl, C<sub>2</sub>-C<sub>8</sub> alkoxyalkyl, C<sub>2</sub>-C<sub>8</sub> haloalkoxyalkyl, C<sub>2</sub>-C<sub>8</sub> alkylthioalkyl, C<sub>2</sub>-C<sub>8</sub> alkylsulfinylalkyl, C<sub>2</sub>-C<sub>8</sub> alkylsulfonylalkyl, C<sub>2</sub>-C<sub>8</sub> alkylcarbonyl, C<sub>2</sub>-C<sub>8</sub> haloalkylcarbonyl, C<sub>4</sub>-C<sub>10</sub> cycloalkylcarbonyl, C<sub>2</sub>-C<sub>8</sub> alkoxycarbonyl, C<sub>2</sub>-C<sub>8</sub> haloalkoxycarbonyl, C<sub>4</sub>-C<sub>10</sub> cycloalkoxycarbonyl, C<sub>2</sub>-C<sub>8</sub> alkylaminocarbonyl, C<sub>3</sub>-C<sub>10</sub> dialkylaminocarbonyl, C<sub>4</sub>-C<sub>10</sub> cycloalkylaminocarbonyl, C<sub>1</sub>-C<sub>6</sub> alkoxy, C<sub>1</sub>-C<sub>6</sub> alkylthio, C<sub>1</sub>-C<sub>6</sub> haloalkylthio, C<sub>3</sub>-C<sub>8</sub> cycloalkylthio, C<sub>1</sub>-C<sub>6</sub> alkylsulfinyl, C<sub>1</sub>-C<sub>6</sub> haloalkylsulfinyl, C<sub>3</sub>-C<sub>8</sub> cycloalkylsulfinyl, C<sub>1</sub>-C<sub>6</sub> alkylsulfonyl, C<sub>1</sub>-C<sub>6</sub> haloalkylsulfonyl, C<sub>3</sub>-C<sub>8</sub> cycloalkylsulfonyl, C<sub>1</sub>-C<sub>6</sub> alkylaminosulfonyl, C<sub>2</sub>-C<sub>8</sub> dialkylaminosulfonyl, C<sub>3</sub>- $C_{10}$  trialkylsilyl or  $G^1$ ; each R<sup>7</sup> and R<sup>10</sup> is independently halogen, cyano, nitro, C<sub>1</sub>-C<sub>4</sub> alkyl, C<sub>1</sub>-C<sub>4</sub> haloalkyl, C<sub>2</sub>-C<sub>4</sub> alkenyl, C<sub>2</sub>-C<sub>4</sub> haloalkenyl C<sub>2</sub>-C<sub>4</sub> alkynyl, C<sub>2</sub>-C<sub>4</sub> haloalkynyl, C<sub>1</sub>-C<sub>4</sub> nitroalkyl, C<sub>2</sub>-C<sub>4</sub> nitroalkenyl, C<sub>2</sub>-C<sub>4</sub> alkoxyalkyl, C<sub>2</sub>-C<sub>4</sub> haloalkoxyalkyl, C<sub>3</sub>-C<sub>4</sub> cycloalkyl, C<sub>3</sub>-C<sub>4</sub> halocycloalkyl, cyclopropylmethyl, methylcyclopropyl, C<sub>1</sub>-C<sub>4</sub> alkoxy, C<sub>1</sub>-C<sub>4</sub> haloalkoxy, C<sub>2</sub>-C4 alkenyloxy, C2-C4 haloalkenyloxy, C3-C4 alkynyloxy, C3-C<sub>4</sub> haloalkynyloxy, C<sub>3</sub>-C<sub>4</sub> cycloalkoxy, C<sub>1</sub>-C<sub>4</sub> alkylthio, C<sub>1</sub>-C<sub>4</sub> haloalkylthio, C<sub>1</sub>-C<sub>4</sub> alkylsulfinyl, C<sub>1</sub>-C<sub>4</sub> haloalkylsulfinyl, C<sub>1</sub>-C<sub>4</sub> alkylsulfonyl, C<sub>1</sub>-C<sub>4</sub> haloalkylsulfonyl, hydroxy, formyl, C<sub>2</sub>-C<sub>4</sub> alkylcarbonyl, C<sub>2</sub>-C<sub>4</sub> alkylcarbonyloxy, C<sub>1</sub>-C<sub>4</sub> alkylsulfonyloxy, C<sub>1</sub>-C<sub>4</sub> haloalkylsulfonyloxy, formylamino, C<sub>2</sub>-

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C<sub>4</sub> alkylcarbonylamino, —SF<sub>5</sub>, —SCN, C<sub>3</sub>-C<sub>4</sub> trialkylsilyl,
     trimethylsilylmethyl or trimethylsilylmethoxy;
each R<sup>8</sup> is independently H, cyano, C<sub>2</sub>-C<sub>3</sub> alkylcarbonyl or C<sub>2</sub>-
     C<sub>3</sub> haloalkylcarbonyl;
each R<sup>9</sup> and R<sup>11</sup> is independently cyano, C<sub>1</sub>-C<sub>3</sub> alkyl, C<sub>2</sub>-
     C<sub>3</sub> alkenyl, C<sub>2</sub>-C<sub>3</sub> alkynyl, C<sub>3</sub>-C<sub>6</sub> cycloalkyl, C<sub>2</sub>-
     C<sub>3</sub> alkoxyalkyl, C<sub>1</sub>-C<sub>3</sub> alkoxy, C<sub>2</sub>-C<sub>3</sub> alkylcarbonyl, C<sub>2</sub>-
     C<sub>3</sub> alkoxycarbonyl, C<sub>2</sub>-C<sub>3</sub> alkylaminoalkyl or C<sub>3</sub>-
     C<sub>4</sub> dialkylaminoalkyl;
each R<sup>12</sup> is independently H, cyano, C<sub>1</sub>-C<sub>4</sub> alkyl, C<sub>1</sub>-
     C_4 haloalkyl, —(C=O)CH<sub>3</sub> or —(C=O)CF<sub>3</sub>;
each G<sup>1</sup> is independently phenyl, phenylmethyl,
     pyridinylmethyl, phenylcarbonyl, phenoxy, phenylethynyl,
     phenylsulfonyl or a 5- or 6-membered heteroaromatic ring,
     each optionally substituted on ring members with up to 5
     substituents independently selected from R<sup>13</sup>;
each R<sup>13</sup> is independently halogen, cyano, hydroxy, amino,
     nitro, —CHO, —C(=O)OH, —C(=O)NH<sub>2</sub>, —SO<sub>2</sub>NH<sub>2</sub>, C<sub>1</sub>-
     C<sub>6</sub> alkyl, C<sub>1</sub>-C<sub>6</sub> haloalkyl, C<sub>2</sub>-C<sub>6</sub> alkenyl, C<sub>2</sub>-C<sub>6</sub> alkynyl, C<sub>2</sub>-
     C<sub>8</sub> alkylcarbonyl, C<sub>2</sub>-C<sub>8</sub> haloalkylcarbonyl, C<sub>2</sub>-
     C<sub>8</sub> alkoxycarbonyl, C<sub>4</sub>-C<sub>10</sub> cycloalkoxycarbonyl, C<sub>5</sub>-
     C<sub>12</sub> cycloalkylalkoxycarbonyl, C<sub>2</sub>-C<sub>8</sub> alkylaminocarbonyl,
     C<sub>3</sub>-C<sub>10</sub> dialkylaminocarbonyl, C<sub>1</sub>-C<sub>6</sub> alkoxy, C<sub>1</sub>-
     C<sub>6</sub> haloalkoxy, C<sub>2</sub>-C<sub>8</sub> alkylcarbonyloxy, C<sub>1</sub>-C<sub>6</sub> alkylthio, C<sub>1</sub>-
     C<sub>6</sub> haloalkylthio, C<sub>1</sub>-C<sub>6</sub> alkylsulfinyl, C<sub>1</sub>-
     C<sub>6</sub> haloalkylsulfinyl, C<sub>1</sub>-C<sub>6</sub> alkylsulfonyl, C<sub>1</sub>-
     C<sub>6</sub> haloalkylsulfonyl, C<sub>1</sub>-C<sub>6</sub> alkylaminosulfonyl, C<sub>2</sub>-
     C<sub>8</sub> dialkylaminosulfonyl, C<sub>3</sub>-C<sub>10</sub> trialkylsilyl, C<sub>1</sub>-
     C<sub>6</sub> alkylamino, C<sub>2</sub>-C<sub>8</sub> dialkylamino, C<sub>2</sub>-
     C<sub>8</sub> alkylcarbonylamino, C<sub>1</sub>-C<sub>6</sub> alkylsulfonylamino, phenyl,
     pyridinyl or thienyl; and
each u and v are independently 0, 1 or 2 in each instance of
     S(=O)_u(=NR^8)_v, provided that the sum of u and v is 0, 1 or
     2;
provided that
(a) the compound of Formula 1 is other than N-1H-
     benzotriazol-1-yl-2-oxo-4-phenyl-3-
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pyrrolidinecarboxamide;

- (b) when Q<sup>1</sup> is a 3-furanyl or 3-pyridinyl ring, then said ring is substituted with at least one substituent selected from R<sup>7</sup>;
- (c) when Q<sup>1</sup> is unsubstituted phenyl, and Q<sup>2</sup> is a phenyl or pyridyl ring, then said Q<sup>2</sup> ring is substituted with R<sup>10</sup> other than optionally substituted phenoxy at a 2-position (relative to the bond of the Q<sup>2</sup> ring to the remainder of Formula 1), and unsubstituted at the 5- and 6-positions (with respect to the 2-position), and R<sup>5</sup> is H or halogen;
- (d) when Q<sup>1</sup> is a phenyl ring and said ring is substituted with R<sup>7</sup> at both ortho positions (relative to the bond to the remainder of Formula 1), then said ring is also independently substituted with R<sup>7</sup> on at least one additional position;
- (e) Q<sup>2</sup> is other than optionally substituted 1H-pyrazol-5-yl; and
- (f) when Q<sup>2</sup> is a 1H-pyrazol-3-yl ring, said ring is substituted at the 1-position with R<sup>11</sup>.

## Ex. 1001, 285:29–288:13.

Dependent claims 2–7 and 22–30 narrow the choices for various substituents on the compounds recited in claim 1. *Id.* at 288:14–48, 291:1–292:44. Independent claim 31 recites the same core compound as claim 1 (i.e., Formula I), but recites fewer options for several of the substituents. *Id.* at 292:45–293:24.

Claims 9–12 and 21 cover an "herbicidal composition," an "herbicidal mixture," or a "mixture" that includes a compound of claim 1. *Id.* at 288:61–289:30, 290:63–67. Claim 13 covers controlling growth of undesired vegetation using an "herbicidally effective amount" of a compound of claim 1. *Id.* at 289:31–34.

F. Asserted Grounds of Unpatentability

We instituted trial based on the following asserted grounds of unpatentability:<sup>2</sup>

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1-3, 9-13, 21-30	§ 112(a)	Enablement
9–13	§ 112(a)	Written Description
1-7, 22-31	§ 102(a)(1)	Olsson <sup>3</sup>
1-7, 22-31	§ 103	Olsson

Inst. Dec. 52; Pet. 5. In support of its patentability challenges, Petitioner relies on two declarations from Dr. David Allen Hunt, Ph.D. (Ex. 1003; Ex. 1029), among other evidence. Patent Owner relies on a declaration from Franck E. Dayan, Ph.D. (Ex. 2011), among other evidence.

#### II. ANALYSIS

## A. Level of Ordinary Skill in the Art

We consider the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art (sometimes referred to herein as "POSA") as of December 2013 (the earliest possible priority date for the challenged claims). *See* Ex. 1001, code (60). Petitioner contends that a such a person would have had "at least a Bachelor's degree in biochemistry or chemistry with several years' experience in agrochemistry, or alternatively, an advanced degree (Masters or Ph.D.) in biochemistry or organic chemistry with emphasis in these same areas," and "may also work

<sup>&</sup>lt;sup>2</sup> Patent Owner does not dispute that the '202 patent is eligible for post-grant review. Pet. 2; *see generally* Resp.; *see also* Inst. Dec. 10 (finding '202 patent eligible for post-grant review).

<sup>&</sup>lt;sup>3</sup> Olsson et al., U.S. Patent Pub. 2007/0123508 A1, published May 31, 2007 ("Olsson," Ex. 1004).

in collaboration with other scientists and/or clinicians who have experience in weed science, plant pathology, or related disciplines." Pet. 13 (citing Ex. 1003 ¶ 66). Although Patent Owner suggests that it has offered a similar proposal, no proposal appears in the Patent Owner Response. See Resp. 50.

In determining the level of skill in the art, we consider factors including the type of problems encountered in the art, prior art solutions to those problems, and the sophistication of the technology. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986). Because Petitioner's proposed definition is consistent with the prior art of record and the sophistication of the technology demonstrated by the record, we apply it here.<sup>5</sup>

<sup>4</sup> For completeness, we note that although it is not cited in the Patent Owner Response, Dr. Dayan's declaration includes the opinion that a person of ordinary skill in the art

would have had a degree (Bachelor's, Masters, or Ph.D.) in biology, biochemistry, or chemistry with several years' experience in agrochemistry, including herbicide discovery and development. This person may also work in collaboration with other scientists and/or clinicians who have experience in weed science, plant pathology, or related disciplines.

Ex. 2011  $\P$  37. This proposal differs from Petitioner's in adding that the degree can be in biology, and in requiring "experience in agrochemistry, including herbicide discovery and development," regardless of degree level. In comparison, Petitioner's proposal does not specify that the degree can be in biology, and does not require the recited "several years' experience in agrochemistry" in connection with an advanced degree. Dr. Dayan states, however, that his opinions would not change if he were to apply Dr. Hunt's proposed level of ordinary skill in the art. *Id.*  $\P$  38.

<sup>&</sup>lt;sup>5</sup> We would reach the same ultimate conclusions in this Decision under Dr. Dayan's proposal. *See* Ex. 2011 ¶ 37.

#### B. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id*.

Petitioner argues that claims 1 and 31 include limitations in a "when" clause, which "only limit[] the claim's scope to the extent the cited condition occurs, and should be read as 'if." Pet. 13–14. Petitioner also states that it has adopted definitions in the '202 patent regarding "several terms related to chemical structures in 5:36–9:9 . . . [and] herbicidal mixtures at 28:61–33:8." *Id.* at 14. Petitioner asserts that the "remaining terms are to be construed in accordance with their ordinary and customary meaning." *Id.* 

Patent Owner asserts that "all claim terms should be given their plain and ordinary meaning, in light of the definitions" in the Specification, and does not propose any express construction for any term. Resp. 10.

Based on the complete record developed at trial, we determine that to resolve the disputes herein, we do not need to expressly construe any claim term. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (explaining that construction is needed only for disputed terms, and only as necessary to resolve the controversy).

#### C. Enablement

A patent's specification must describe the claimed invention and "the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). The enablement requirement asks whether "the specification teach[es] those in the art to make and use the invention without undue experimentation." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). In analyzing whether any required experimentation is undue, we consider factors such as:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

*Id.* Whether a specification is enabling is determined as of the filing date of the application. *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004).

Petitioner asserts that the Specification fails to enable both (1) *use* as herbicides of the full scope of the compounds encompassed by claims 1–3, 9–13 and 21–30; and (2) *how to make* the full scope of the compounds encompassed by a subset of these claims (i.e., claims 1–3, 9–13, 21, 23, and 27–30). Pet. 15, 32.

On the full trial record, we determine that Petitioner has demonstrated by a preponderance of the evidence that the Specification fails to enable the *use* as herbicides of the full scope of compounds of claims 1–3, 9–13 and 21–30. Because this determination reaches all claims challenged for lack of enablement, we need not and do not reach Petitioner's argument that the Specification fails to enable *how to make* the full scope of the compounds of claims 1–3, 9–13, 21, 23, and 27–30. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written

decision addressing all of the claims it has challenged"); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, Nos. 2019-1594, -1604, -1605, 2020 WL 2071962, at \*4 (Fed. Cir. Apr. 30, 2020) (non-precedential) (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding" and, thus, agreeing that the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims").

We first briefly summarize the parties' contentions, then turn to our analysis.

# 1. Brief Overview of the Parties' Contentions

Petitioner asserts that claim 1 "covers over a billion[] compounds," Pet. 18 (citing Ex. 1003 ¶ 139), but the '202 patent lacks sufficient guidance or working examples across the full scope of claim 1 to allow a person of ordinary skill in the art to determine which of the claimed compounds have herbicidal activity without undue experimentation. *Id.* at 18–20 (citing Ex. 1003 ¶¶ 140–155; Exs. 1007, 1011–1016). According to Petitioner, the approximately 350 compounds tested in the Specification for herbicidal activity "fail[] to enumerate the majority of the substituents available at each position" of the claimed genus, and "indicate[] that substitutions, particularly at the Q<sup>1</sup>, Q<sup>2</sup>, R<sup>1</sup>, and R<sup>6</sup> positions, can strongly impact herbicidal activity and even eliminate it." *Id.* at 16 (citing Ex. 1003 ¶¶ 135, 136, 144, 151, 155–172), 19–20. Petitioner asserts that small substitutions, e.g., an alkyl instead of a hydrogen, can dramatically affect herbicidal activity by altering properties such as lipophilicity, metabolism, plant uptake, and translocation, yet the '202 patent fails to teach a structure-activity relationship, mode of action, or what enzymes or binding sites (if any) the claimed compounds

affect. *Id.* at 17, 19–20. Petitioner argues that "several of the compounds tested failed to exhibit any herbicidal activity at the high screening levels (*e.g.*, 1000 and 500 g ai/ha), which would indicate that a POSA would not be able to use the claimed compounds as an herbicide without undue experimentation, if at all." *Id.* at 16–17 (citing Ex. 1003 ¶ 137); *see also id.* at 22–30 (citing, *e.g.*, Ex. 1003 ¶¶ 153–172).

Patent Owner contends that Petitioner fails to distinguish between the legal standards for compound claims and method of use claims. Patent Owner argues that compound claims 1–3 and 21–30 are enabled because an ordinarily skilled artisan "would not have had a reason to doubt" the Specification's teaching that the compounds are herbicides. Resp. 18. As to both these compound claims and the claims that recite use as an herbicide (claims 9–13), Patent Owner argues they are enabled because extensive screening is understood to be a normal part of herbicide development (*id.* at 24), and the examples in the Specification "include sufficient variation with respect to at least steric and electrostatic properties . . . to allow a person of skill in the art to utilize standard modeling techniques . . . to guide the synthesis and screening of additional molecules falling within the genus" without undue experimentation (*id.* at 38 (citing Ex. 2011 ¶ 50), 43).

# 2. Analysis

We start with Patent Owner's contention that the enablement standard is different for compound and method claims. Resp. 17; see also id. at 2. With respect to the compound claims, Patent Owner argues that "[a] disclosure of practical utility 'must be taken as in compliance with the enabling requirement of . . . § 112 unless there is reason to doubt the objective truth of the statements contained therein,' such as when the

statement 'involve[s] implausible scientific principles." *Id.* at 18 (quoting *In re Brana*, 51 F.3d 1560, 1566 & n.17 (Fed. Cir. 1995)). Patent Owner argues that Petitioner has presented no evidence that the Specification's teaching that the compounds are herbicides<sup>6</sup> is implausible or unreliable. Resp. 18; *see also* Ex. 2011 ¶ 47 (asserting that based on the Specification's biological testing results, "a person of skill in the art would have no reason to doubt that compounds within the full scope of claim 1 of the '202 patent would exhibit herbicidal activity").

Even assuming Patent Owner were correct that there is a different enablement standard for compound and method claims, Petitioner has raised reasons why persons of ordinary skill in the art would doubt that the '202 patent enables the full scope of the claimed compounds as herbicides. As will be discussed below, Petitioner has credibly established that in view of the breadth of the claims, the relative lack of diversity of the compounds actually tested, and the test results showing inactivity and trends toward inactivity for compounds that deviated from the narrow range of structures tested, a person of ordinary skill in the art has reasonable basis to doubt that compounds within the full scope of claim 1 of the '202 patent exhibit herbicidal activity. Accordingly, we proceed to analyzing the parties' arguments for claims 1–3, 9–13, and 21–30 under the factors set forth in *In re Wands*. We begin with claim 1, then turn to the remaining claims.

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<sup>&</sup>lt;sup>6</sup> The only asserted utility taught in the Specification for the disclosed compounds is herbicidal activity. *See, e.g.*, Ex. 1001, 1:5–7, 155:56–57; Ex. 1003 ¶¶ 46–48, 130–33; Resp. 17.

a. Nature of the Invention, Predictability or Unpredictability of the Art, and Relative Skill in the Art

The field of the invention is agrochemicals—specifically, herbicides. *See, e.g.*, Ex. 1001, codes (54), (57). The parties agree that the agrochemical field is "well-developed and mature." Resp. 49; Tr. 17:13–16 (Petitioner's counsel acknowledging that agrochemical field is mature in some regards); *see also* Ex. 1006, 85 (discussing multibillion dollar global herbicide market), 86 (referencing 184 herbicides marketed between 1970 and 2005).

The parties also agree that level of ordinary skill in the art is relatively high. *See supra* Section II.A; *see also* Resp. 50 (acknowledging that the level of skill in the art is high); Tr. 15:18 (Petitioner's counsel acknowledging that the level of skill in the art is relatively high).

The parties also agree that ordinarily skilled artisans routinely use field screening tests and computational modeling techniques such as quantitative structure-activity relationship models ("QSAR").<sup>7</sup> *See, e.g.*, Resp. 49; Ex. 2011 ¶¶ 20, 27, 28 (discussing common field screening tests); Ex. 1003 ¶ 39 (acknowledging use of screening tests in herbicide development); Ex. 2005, 488–89; Exs. 2017, 2022, 2024 (all relating to use of QSAR in herbicide development); *see also* Tr. 7:19–8:5 (Petitioner's counsel acknowledging that QSAR is used in the field).

Despite the maturity in the field and relatively high level of ordinary skill in the art, the parties agree that the art is unpredictable. *See* Pet. 19–20 (discussing lack of predictability); Ex. 1003 ¶¶ 142–143; Resp. 50 ("As both

<sup>&</sup>lt;sup>7</sup> Comparative molecular field analysis ("CoMFA") is a form of QSAR. Ex. 1028, 39:20–21. We use the term QSAR to encompass both QSAR and CoMFA.

parties agree, and the Board recognized, chemistry and biotechnology areas such as the agrochemical field are generally understood to be 'unpredictable arts.'"). For example, Petitioner's expert Dr. Hunt testifies (and Patent Owner does not dispute) that small structural changes can result in major differences in biological activity, and even seemingly minor substitutions can have "dramatic effects on activity by altering such phenomena as lipophilicity, metabolism, plant uptake, and translocation." Ex. 1003 ¶ 142 (citing Exs. 1011, 1012); see also id. ¶ 42 (citing Ex. 1007), ¶ 43, ¶ 143 (citing Ex. 1026).

Based on the full record developed at trial—much of it undisputed as discussed above—we find that the field of invention is mature and the level of ordinary skill in the art is relatively high, which both weigh in favor of enablement, but the art is unpredictable, which weighs against enablement.

## b. Breadth of Claims

It is undisputed that claim 1 is extremely broad, "cover[ing] more than a billion different compounds." Ex. 1003 ¶ 139; see also Ex. 1029 ¶ 8 (asserting that claim 1 covers more than  $10^{32}$  compounds); Tr. 32:4–7 (Patent Owner's counsel acknowledging that the number of compounds covered by the claims is not disputed). More specifically, claim 1 recites "[a] compound selected from Formula I, N-oxides and salts thereof:

wherein each of ten different substituents (Q<sup>1</sup>, Q<sup>2</sup>, Y<sup>1</sup>, Y<sup>2</sup>, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, and R<sup>6</sup>) are independently selected from a wide range of substituents. Ex. 1001, 285:29–288:13; Ex. 1003 ¶ 49. The Q<sup>1</sup>, Q<sup>2</sup>, R<sup>1</sup>, and R<sup>6</sup> groups alone each recite "well over a thousand possible independent options" spanning a wide range of size and electrostatic properties. Ex. 1003 ¶ 49 (citing Ex. 1001, 285:44–286:51, 286:59–287:6, 287:33–38); Reply 16–22; Ex. 1029 ¶¶ 34, 37, 39, 45, 49.

We find that the breadth of the claims weighs against enablement.

## c. Direction or Guidance

We find that despite the claim breadth, the direction or guidance in the Specification on how to practice the full scope of the claims is relatively scant. For example, Petitioner correctly notes that the Specification does not disclose the mode of action of the claimed compounds. Pet. 19–20 (citing Ex. 1003 ¶ 146). Patent Owner does not dispute this, but instead argues that a patent need not disclose an invention's method of action. Resp. 44.

Although Patent Owner is correct that a patent need not disclose an invention's method of action (*see, e.g., Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014)), the record reflects that such information would have helped ordinarily skilled artisans understand how changes to a compound's structure impact herbicidal activity. *See, e.g.*, Ex. 1003 ¶ 146 (discussing relationship between compound structure and biological activity). Without this information, by Patent Owner's own admission and as will be further discussed below, to practice the full scope of the claims, ordinarily skilled artisans must engage in iterative QSAR

modeling to develop a structure-activity relationship themselves. See, e.g., Resp. 34 ("[A] skilled artisan could have used the biological data from the specification to develop a structure-activity relationship, and on the basis of that relationship, select compounds likely to have herbicidal activity to synthesize and test in the field."), 3 (referencing "common modeling techniques that are regularly used by persons skilled in the art when developing herbicides to establish structure-activity relationships"); Ex. 2011 ¶ 24.

The record also reflects that knowing a mode of action would have assisted the QSAR modeling process. *See* Reply 13 n.4; Ex. 1033, 40 ("An understanding of a chemical mode/mechanism of action is highly sought when developing (Q)SARs."); Ex. 1029 ¶ 22. Accordingly, absence of this information in the Specification reduces the guidance available to an ordinarily skilled artisan and increases the quantity of experimentation needed to practice the full scope of the claims. *See* Ex. 1029 ¶¶ 21–22; *see* 

<sup>&</sup>lt;sup>8</sup> Relying on testimony from its expert Dr. Dayan, Patent Owner also argues that it is "uncommon for the mechanism to be known during herbicide discovery" (Resp. 54 (citing Ex. 2011 ¶ 19)), and that QSAR modeling is "more predictive of herbicidal activity than the analysis of whether a particular compound binds to a target site" (*id.* at 8 (citing Ex. 2011 ¶¶ 22, 25); *see also id.* at 43). We do not credit these arguments, because Dr. Dayan's testimony on these points is little more than *ipse dixit* and lacks corroboration. *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) ("[T]he Board is entitled to weigh the declarations and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations."). Additionally, despite Patent Owner's efforts to downplay the utility of knowing a mode of action, it is notable that almost half of Dr. Dayan's 150+ publications relate to the mode of action of herbicides, while only a few concern QSAR studies. Ex. 1028, 35:25–36:7, 42:16–19; Reply 13 n.4.

also Wyeth and Cordis Corp. v. Abbott Labs., 720 F.3d 1380, 1385 (Fed. Cir. 2013) (finding that where "[t]he specification offers no guidance or predictions about particular substitutions that might preserve the [claimed activity]", "[t]he resulting need to engage in a systematic screening process for each of the many rapamycin candidate compounds is excessive experimentation").

The Specification does include a number of working examples, which we discuss in the next section. Patent Owner also correctly asserts that the Specification teaches several herbicide formulations and mixtures and how to test mixtures, and reports test results for several mixtures. Resp. 29 (citing Ex. 1001, 149:1–155:15, 166:60–173:38), 34 (citing Ex. 1001, cols. 275–285, 276:29–44). As Patent Owner recognizes, however, Petitioner "do[es] not challenge anything with respect to formulating the compounds as herbicides." *Id.* Thus, we find that this additional information regarding formulations and mixtures does not bear on whether the Specification provides an ordinarily skilled artisan with direction or guidance on how changing substituents outside of the limited examples disclosed in the Specification would impact herbicidal activity.

In view of the above, we conclude that aside from the working examples (discussed separately below), the Specification lacks meaningful direction or guidance, which weighs against enablement.

d. Presence or Absence of Working Examples

The Specification provides field test results for herbicidal activity for 335 compounds using different concentrations of the compounds on

different plant species.<sup>9</sup> Resp. 30 (citing Ex. 1001, cols. 82–285); *see also id.* at 30–33 (detailing the compounds tested, types of tests, and application rates), 44–45; Ex. 1003 ¶ 55. These 335 compounds "represent only a minute fraction," or "less than 1/10,000 of a percent," of the total number of compounds encompassed by claim 1. Ex. 1003 ¶ 147; Ex. 1029 ¶ 7; Pet. 20. Thirteen of these compounds were inactive in every test performed. Pet. 22 (citing Ex. 1001, Tables A–H5; Ex. 1003 ¶¶ 153–54).

Patent Owner correctly asserts that enablement does not require either (1) the Specification to disclose testing of "each" claimed compound and modifying of "each" claimed variable, or (2) that an ordinarily skilled artisan "know in advance precisely all of the compounds that will show herbicidal activity." Resp. 45, 35, 51; see also Sur-reply 3, 8–9. But "[t]he specification must contain sufficient disclosure to enable an ordinarily skilled artisan to make and use the entire scope of the claimed invention at the time of filing." MagSil Corp. v. Hitachi Global Storage Techs., Inc., 687 F.3d 1377, 1382 (Fed. Cir. 2012) (emphasis added); see also id. at 1382 ("[T]he scope of the claims must be less than or equal to the scope of the enablement."). Thus, the salient question here is whether the working examples demonstrate sufficient variation to guide the selection and use of other compounds within the full scope of the claims.

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<sup>&</sup>lt;sup>9</sup> Petitioner contends that the Specification discloses testing for 351 compounds. *See, e.g.*, Pet. 21; Ex. 1003 ¶ 55. However, we agree with Patent Owner that while the Specification discloses the synthesis of 351 compounds, only 335 of them were tested for herbicidal activity. Resp. 30; Ex. 1001, cols. 174–181 (describing synthesized compounds), 181–285 (describing test results). In any event, we would reach the same opinions herein using Petitioner's value of 351 compounds tested.

Petitioner argues that the tested compounds are of limited scope and several showed inactivity, such that an ordinarily skilled artisan is unable to determine which other compounds across the full scope of the claim have herbicidal activity without undue experimentation. *See, e.g.*, Pet. 23. Patent Owner argues that "the data disclosed in the specification suggests that the vast majority" of claimed compounds have herbicidal activity, and "there is sufficient variation to allow skilled artisans to apply standard modeling techniques such as QSAR and CoMFA to guide the selection of other molecules falling within the genus for synthesis and screening." Resp. 67, 46. We find that Petitioner has the better position.

We agree with Petitioner's expert Dr. Hunt that the test data reported in the Specification "is clustered around a narrow range of structures" compared to what is claimed. Ex. 1029 ¶ 11; see also Reply 7. Like the parties, we focus on the Q¹, Q², R¹, and R⁶ positions recited in claim 1. Petitioner establishes, and Patent Owner does not dispute, that claim 1 encompasses thousands of choices for each of these positions. Pet. 7; Ex. 1003 ¶¶ 49, 139, 149, 158, 162. Despite this breadth, the test data spans only about seventy five choices for Q¹, fifty four choices for Q², seven choices for R¹, and six choices for R⁶. See Resp. 36–38; Ex. 2011 ¶ 50.

Drilling deeper into the  $Q^1$  and  $Q^2$  positions, the tested substituents are overwhelmingly phenyls. Ex.  $1003 \, \P \, 148$ . At  $Q^1$  and  $Q^2$ , only about thirty six and eighteen of the tested compounds, respectively, had a substituent other than a phenyl or substituted phenyl. *Id.*; Ex.  $1029 \, \P \, 43$ , 46; *see also* Ex.  $2011 \, \P \, 50$  (listing the different tested substituents). Four of the thirteen inactive compounds had pyrazoles at  $Q^1$ , and three other compounds with pyrazoles at  $Q^1$  showed only slight activity. Pet. 22-23

(citing Ex. 1001, Tables A–H5; Ex. 1003 ¶ 156); *see also* Ex. 1003 ¶¶ 144, 157–58; Ex. 1029 ¶ 44. We credit Dr. Hunt's testimony that this data "indicates to a POSA that *at least some* claimed compounds with heterocyclic rings at the Q¹ position, and particularly 5 membered heteroaromatic rings, like a pyrazole, could have little or no utility as an herbicide." Ex. 1003 ¶ 157. We also credit his testimony that based on this data, an ordinarily skilled artisan would conclude that "activity might depend upon the nature and location of additional substituent groups on a heterocyclic compound." *Id.*; *see also* Ex. 1029 ¶ 44.

Thus, the examples in the Specification "demonstrate the lack of predictability that occurs when  $Q^1$ ,  $Q^2$  are a compound other than a substituted or un-substituted phenyl." Ex.  $1003 \, \P \, 155$ . Yet thousands of heterocyclic groups are possible at  $Q^1$ , which are not exemplified in the biological data. *Id.* ¶ 158. For example, claim 1 permits  $Q^1$  to be substituted off carbon and nitrogen atoms with  $R^7$  and  $R^9$ , respectively, but no  $R^7$  and  $R^9$  sub-groups were tested on heterocyclic  $Q^1$  groups, even though heterocycles comprise the vast majority of the available substituents at  $Q^1$ . Ex.  $1029 \, \P \, 45$ . And as discussed above, small changes can have a large impact on biological activity. Ex.  $1003 \, \P \, 42$ . In view of the above, we credit Dr. Hunt's testimony that

 $<sup>^{10}</sup>$  Although claim 1 places some limits on using pyrazoles at  $Q^2$ , it does not restrict using pyrazoles and most heteroaromatic and heterocyclic compounds at  $Q^1$ . Ex. 1003 ¶ 157.

[a] POSA would need to engage in undue experimentation just to determine which Q¹ groups within the scope of claim 1 could have herbicidal activity, given the large breadth of the molecules covered, the lack of examples in the specification—particularly relating to heterocompounds, and the unpredictability evidenced by the few compounds actually tested in the '202 Patent.

# *Id.* ¶ 158 (footnote omitted).

Similarly, with respect to Q<sup>2</sup>, one-third of tested compounds with a non-phenyl Q<sup>2</sup> had little or no activity. Ex. 1003 ¶¶ 159–162; Ex. 1029 ¶¶ 47–48. The lack of or diminished activity across such a large percentage of the few non-phenyl groups tested at Q<sup>2</sup> indicates that activity of compounds with heteroaromatics or other of the recited non-phenyl groups at Q<sup>2</sup> is unpredictable. Ex. 1003 ¶¶ 159–162; Ex. 1029 ¶¶ 47–48. Additionally, the R<sup>10</sup> and R<sup>11</sup> sub-group substituents tested off of the non-phenyl Q<sup>2</sup> groups were extremely limited. Ex. 1029 ¶¶ 49–50. Thus, we credit Dr. Hunt's testimony that a person of ordinary skill in the art would need to engage in undue experimentation to understand which Q<sup>2</sup> groups within the scope of claim 1 would have herbicidal activity. Ex. 1003 ¶ 162; Ex. 1029 ¶¶ 47–50.

Turning to the R¹ position, claimed R¹ options extend to moieties having as many as ten carbons, but in the tested compounds R¹ was either hydrogen or one of only six other substituents. Ex. 1003 ¶¶ 149, 169. The six non-hydrogen substituents were limited to small molecules having fewer than three carbons, and activity tended to decrease as R¹ got larger. *Id.* ¶¶ 149, 170; Ex. 1029 ¶¶ 33, 38; *see also* Ex. 2011 ¶ 52 (listing tested substituents). Specifically, the highest herbicidal activity is shown for methyl or hydrogen substituents, and the larger ethyl and propyl substituents

generally had lower activity. Ex.  $1003 \, \P \, 170$ . Dr. Hunt compares the structures of tested  $R^1$  substituents to the structures of some exemplary claimed, but untested,  $R^1$  substituents, and demonstrates that the tested and untested substituents differ significantly in size and location of electron withdrawing or donating groups. Ex.  $1029 \, \P \, 37$ ; see also id.  $\P \, \P \, 38-39$ . The majority of the claimed substituents available at  $R^1$  "would be larger (and in most cases, substantially larger)" than the  $R^1$  substituents tested in the '202 patent, despite the "pattern of diminishing activity as the alkyls at  $R^1$  increased in size." *Id.*  $\P \, 38$ .

The testing in the Specification also does not encompass any of the eight cyclic aromatics groups contemplated by the claimed sub-group  $G^1$  at the  $R^1$  position. Ex.  $1029 \, \P \, 34$ . Each  $G^1$  substituent can be substituted with up to five substituents selected from  $R^{13}$ , where  $R^{13}$  is selected from an additional thirty nine groups that vary in size from a single atom to large subgroups containing up to eight or ten carbons. *Id.* The electrostatic properties and the location of the electron donating or withdrawing groups in the claimed  $R^{13}$  substituents vary widely. *Id.* This vast variation in sterics and electronics possible at  $G^1$ , however, is unexplored in the Specification. *Id.*  $\P \, 39$ .

In view of the above, we credit Dr. Hunt's testimony that [g]iven the very limited experimental data provided in the '202 Patent, coupled with the fact that the experimental data demonstrates that increasing group size could reduce (and possibly eliminate) herbicidal activity, a POSA would not be able to use the full scope of the compounds of claim 1—including all of the potential substituents of the R¹ group, without undue experimentation.

Ex.  $1003 \, \P \, 171$ ; see also Ex.  $1029 \, \P \, 40$  ("[A] person of ordinary skill in the art would not consider the testing performed with regard to . . . the [R<sup>1</sup>] position[] to be either diverse or representative, given the breadth of possible substituents, and the very limited scope of the testing.").

Turning to the R<sup>6</sup> position, claimed R<sup>6</sup> options extend to moieties having as many as ten carbons, but in the tested compounds R<sup>6</sup> was hydrogen or one of only five other claimed substituents. Ex. 1003 ¶¶ 149, 166; Ex. 2011 ¶ 54. The data shows a lack of activity for R<sup>6</sup> substituents larger than hydrogen or having more than one carbon atom. Ex. 1003 ¶¶ 163, 166–68; Ex. 1029 ¶¶ 11, 38. Based on this data, Dr. Hunt testifies that because the R<sup>6</sup> position appears to be sensitive to large molecules, "there is a significant possibility that the vast majority of the claimed compounds (i.e., those compounds having larger R<sup>6</sup> groups) could have no activity." Ex. 1029 ¶ 12.

As he did for R<sup>1</sup>, Dr. Hunt also compares the structures of tested R<sup>6</sup> substituents to the structures of some exemplary claimed, but untested, R<sup>6</sup> substituents. *Id.* ¶ 37. This comparison demonstrates that the tested and untested substituents differ significantly in the size and location of electron withdrawing or donating groups, with the untested R<sup>6</sup> substituents being generally much larger than the tested R<sup>6</sup> substituents. *Id.*; *see also id.* ¶¶ 38–39; Ex. 1003 ¶¶ 166–67. In view of the above, we credit Dr. Hunt's testimony that

[g]iven the very limited experimental data provided in the '202 Patent, coupled with the fact that the experimental data demonstrates that even small substitutions at the R<sup>6</sup> position do not appear to be well-tolerated, (the only alkenyls and alkenyls tested at R<sup>6</sup> had no activity, and no group having more than 1 carbon atom was shown to have herbicidal activity), a POSA would not be able to use the full scope of the compounds of claim 1—including all of the potential substituents of the R<sup>6</sup> group, without undue experimentation.

Ex. 1003 ¶ 168; see also id. ("[T]he biological data includes no information regarding the vast majority of the claimed  $R^6$  substituents and indicates that for multiple  $R^6$  substituents, there may be little or no herbicidal activity.").

In sum, we find that small structural changes can result in major differences in biological activity, and this is borne out in the data in the patent. Id. ¶¶ 42–43; see also id. ¶¶ 142, 143, 145–46 (addressing structural features that impact activity); Ex. 1029 ¶ 30. The working examples in the Specification are clustered around a narrow range of structures compared to the full scope of the claimed structures. See, e.g., Ex. 1029 ¶ 11. The lack of significant structural variation in the working examples is particularly important because "[w]hat little testing deviates from this narrow area of testing demonstrates a much higher rate of inactivity and diminished activity." *Id.*; see also Reply 7 (citing Ex. 1003 ¶¶ 163–172; Ex. 1029 ¶¶ 11-12). The working examples fail to provide sufficient variation to allow an ordinarily skilled artisan to understand the impact the claimed substituents at each position, and particularly the Q1, Q2, R1, and R6 positions, will have, especially when considered in combination with the options at other positions. See, e.g., Ex. 1003 ¶¶ 136–37, 144. We credit Dr. Hunt's testimony that there is a vast gap between the scope of the claims and the guidance provided in the Specification. Ex. 1003 ¶¶ 138–172; Ex. 1029 ¶¶ 29–50.

Patent Owner appears to argue that the biological test results reported in the Specification, standing alone, enable the full scope of the claims. Specifically, its expert Dr. Dayan testifies: "Based on [the] testing [in the Specification], a person of skill in the art would have no reason to doubt that compounds within the full scope of claim 1 of the '202 patent would exhibit herbicidal activity." Ex. 2011 ¶ 47. Dr. Dayan also testifies that the variation in steric and electrostatic properties across the tested substituents would lead a person of ordinary skill in the art to expect at least some herbicidal activity across the claimed but untested substituents. Ex. 2011 ¶¶ 52–57; see also Resp. 38–42.

For example, Dr. Dayan testifies that the seven tested  $R^1$  substituents vary in size, "with hydrogen being the smallest and tertiary-butoxycarbonyl being the largest," and in electrostatic properties, "with the hydroxyl groups representing a polar group and the alkyl groups representing non-polar groups." Ex. 2011 ¶ 52. Based on the test results, Dr. Dayan concludes that there is "clear evidence that position  $R^1$  contributes to herbicidal activity across a variety of groups," and that "one would expect at least some herbicidal activity across the list of substituents that the '202 patent identifies for  $R^1$ , with smaller groups being the most promising candidates for further screening." Id. ¶ 53. Dr. Dayan performs a similar analysis for the  $R^6$ ,  $Q^1$ , and  $Q^2$  positions and opines that because the tested structures vary in size and polarity, a person of ordinary skill in the art would expect at least some herbicidal activity across all claimed substituents. Id. ¶¶ 54–57.

We find that Dr. Dayan's testimony on these points lacks sufficient supporting analysis. In opining that the tested substituents are representative of the steric and electrostatic properties across the claimed substituents, Dr. Dayan merely compares the properties of the tested substituents to each other. See, e.g., id. ¶¶ 52–56. He does not expressly compare them to the properties of the many remaining, untested substituents within the scope of the claims. See id.; see also Reply 14 ("At best, [Dr.] Dayan testified that the positive activity . . . at each substituent" suggests that the position is involved in herbicidal activity, "not that the tested compounds were sufficient to provide any reasonable expectation of success as to the billions of structurally diverse compounds covered" by the claims.). And although Dr. Dayan acknowledges that several tested compounds showed no herbicidal activity, he does not expressly explain how he took these compounds into account in nevertheless concluding that an ordinarily skilled artisan would expect at least some activity across all claimed substituents. See, e.g., Ex. 2011 ¶¶ 54–56 (noting exceptions to herbicidal activity).

As one example, Dr. Dayan acknowledges the lack of activity shown in the data for substituents larger than hydrogen at the R<sup>6</sup> position, but does not explain the impact of that data on the remaining claimed substituents. *See id.* ¶ 54 (Dr. Dayan noting that activity is "not as favored by larger alkyl groups" at R<sup>6</sup>, but nevertheless concluding that "one would expect at least some herbicidal activity" across all claimed R<sup>6</sup> substituents). In contrast, Dr. Hunt compares the size and properties of the R<sup>6</sup> substituents that showed no activity with the size and properties of other claimed but untested R<sup>6</sup> substituents. Ex. 1003 ¶¶ 163, 166–68; Ex. 1029 ¶¶ 37, 38. This comparison indicates that the majority of R<sup>6</sup> substituents are larger than the

tested substituents, such that the vast majority of the claimed compounds (i.e., those with compounds having R<sup>6</sup> substituents larger than those tested), could have no herbicidal activity. Ex. 1003 ¶ 167; Ex. 1029 ¶¶ 12, 37, 38. Thus, we find that the data in the Specification regarding at least position R<sup>6</sup> gives a person of ordinary skill in the art reason to doubt that substantially all compounds within the full scope of claim 1 of the '202 patent would exhibit herbicidal activity. Ex. 1003 ¶ 163; Ex. 1029 ¶¶ 11, 12, 38; *In re Surrey*, 370 F.2d 349, 355 (CCPA 1966) ("[W]here the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds there should be a disclosure which gives a reasonable assurance that all, or substantially all of them are useful.").

Moreover, Petitioner, with the support of Dr. Hunt's testimony, establishes that merely testing one or two small polar substituents and a number of other small non-polar substituents does not adequately represent the electrostatic and steric properties of the entire claimed space. Reply 16; Ex. 1029 ¶ 30. Dr. Dayan overlooks that it is also important where on the molecule the polarity or electron donating/receiving group is located. Ex. 1029 ¶ 30; *see also id.* ¶ 23. With the support of Dr. Hunt's testimony, Petitioner establishes, and Patent Owner does not dispute, that the tested and untested substituents differ significantly in size and location of electron withdrawing or donating groups. *Id.* ¶¶ 37–39; Reply 16–20.

The record also reflects that factors beyond sterics and electrostatics affect biological activity. *See, e.g.*, Ex. 1003 ¶¶ 142–46; Pet. 19. As but one example, it is well known that the lipophilicity (or log P) of a compound can significantly impact biological activity. Ex. 1029 ¶ 24. The log P values for some of the claimed  $Q^1$  substituents span several orders of magnitude. *Id.*;

Pet. 19. But neither the '202 patent nor Dr. Dayan's declaration mentions lipophilicity, much less analyzes whether the tested compounds are representative of the full scope of lipophilicity values across the claimed compounds. Ex. 1029 ¶ 24; Reply 13.

In view of the above, we find that the scope of the working examples is narrow compared to the scope of the claims.

Patent Owner raises several additional arguments in response. For one, Patent Owner argues that Dr. Hunt's testimony regarding inactivity for larger R<sup>6</sup> substituents is "pure, unsupported speculation" because Petitioner merely relies on a "trend' of decreasing activity for larger R<sup>1</sup> and R<sup>6</sup> substituents," but "did no testing or modeling to back up its claim." Surreply 11. Patent Owner argues that such "conclusory expert testimony" is "not sufficient to provide clear and convincing evidence of a lack of enablement." *Id.* at 11–12.

Patent Owner's arguments are unavailing. First, Patent Owner seeks to hold Petitioner to too high a legal standard. Petitioner has the burden of establishing unpatentability based on a preponderance of the evidence, not clear and convincing evidence. 35 U.S.C. § 326(e). Second, Petitioner does not merely rely on the "trend" of decreasing activity to conclude that larger R<sup>6</sup> groups would likely be inactive. Rather, Dr. Hunt's testimony is based on data in the Specification itself showing a lack of activity for compounds 265 and 266, which were tested in both preemergence and postemergence tests at the highest concentration level (1000 g ai/hg). Ex. 1001, cols. 184, 200; Ex. 1003 ¶¶ 153, 163, 166, 168; Ex. 1029 ¶¶ 35–36.

Compounds 265 and 266 respectively have a propargyl and allyl at R<sup>6</sup>, and represent two of only six compounds tested where R<sup>6</sup> was not hydrogen,

and are the only two compounds tested that have more than one carbon at  $R^6$ . Ex. 1001, col. 181 (Index Table C); Ex. 1003 ¶¶ 163, 166, 168; Ex. 1029 ¶¶ 35–36; *see also* Ex. 2011 ¶ 50 (listing tested options for  $R^6$ , i.e., H, allyl, Me, OH, OMe, and propargyl). Thus, although the Specification provides a limited range of variation for  $R^6$  substituents, the provided data shows that no compound having a substituent other than hydrogen or having more than one carbon was active. Yet claim 1 recites that  $R^6$  can be  $C_{1-6}$  alkyls, alkenyls, and alkynyls, a variety of highly functionalized alkyl groups with up to ten carbons (including carbonyls, alkoxys, haloalkyls, etc.), and phenyls and 5–6 membered heteroaromatics optionally substituted with up to 5 members (via the  $G^1$  limitations), each of which themselves could be a wide variety of members, including large groups with up to ten carbons and other aromatics. Ex. 1003 ¶ 166.

Thus, the data in the Specification supports Dr. Hunt's opinion that compounds with R<sup>6</sup> substituents larger than hydrogen or more than one carbon are unlikely to be active. Ex. 1003 ¶ 168; Ex. 1029 ¶ 12. We acknowledge that compounds 265 and 266 represent only two data points, but such paucity is created by the minimal disclosure of the '202 patent. The '202 patent provides only six different options at R<sup>6</sup>, and only compounds 265 and 266 test R<sup>6</sup> substituents larger than hydrogen or having more than one carbon. *See, e.g.*, Ex. 2011 ¶ 50 (listing variability at R<sup>6</sup>); Ex. 1003 ¶ 163; Ex. 1029 ¶¶ 35–36. We also find Dr. Hunt's opinion about inactivity at R<sup>6</sup> better supported and thus more credible than Dr. Dayan's conclusory opinion that "one would expect at least some herbicidal activity across the list of substituents that the '202 patent identifies for R<sup>6</sup>." Ex. 2011 ¶ 54. As discussed above, although Dr. Dayan acknowledges that "[a]ctivity is not as

favored by larger alkyl groups" at  $R^6$ , he does not compare the relative sizes of the tested  $R^6$  substituents to the claimed but untested  $R^6$  substituents. *Id.*; *see also id.* ¶ 59. A large swath of the claimed  $R^6$  substituents are larger than hydrogen and include more than one carbon (*see, e.g.*, Ex. 1003 ¶ 166), and thus Dr. Dayan's conclusion that one would expect at least some herbicidal activity across the list of substituents that the '202 patent identifies for  $R^6$  is inconsistent with the data, the scope of the claim, and lacks credible support.

Patent Owner seeks to justify the limited number of working examples in the Specification by arguing that "[e]arly filing of an application with its disclosure of novel compounds" is to be encouraged, and that requiring "specific testing on all the compounds encompassed by the claims to demonstrate the utility of the genus would have delayed disclosure." Resp. 20–21 (citing *In re Bundy*, 642 F.2d 430, 434 (CCPA 1981)). However, where an inventor seeks a patent "in exchange for his disclosure of a group of compounds there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful." Surrey, 370 F.2d at 355. A patentee is "not entitled to a claim for a large group of compounds merely on the basis of showing that a selected few are useful and a general suggestion of a similar utility in the others." *Id.* Similar to *Surrey*, we find that here, the Specification "fail[s] to provide those of ordinary skill in the art . . . reasonable assurance, as by adequate representative examples, that the compounds falling within the scope of the claim will possess the asserted usefulness." *Id.* at 356. We also note that enablement serves to prevent "overbroad claiming that might otherwise attempt to cover more than was actually invented." MagSil, 687 F.3d at 1381. "Thus, a patentee chooses

broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage." *Id.* That is the situation here.

Patent Owner argues that the '202 patent "provides significantly more variation and more examples than the patents of [Petitioner's] own expert, Dr. Hunt." Resp. 46. Patent Owner also argues that "Dr. Hunt's patents show that the level of disclosure in the '202 patent is standard in the herbicide field, and show that it is common for herbicide patents to contain only a few examples while covering a large number of compounds." *Id.* at 48. Patent Owner's arguments are unavailing, because they presuppose that Dr. Hunt's patents are enabled. But whether those patents are enabled is not at issue here, and we do not undertake such an analysis. We also find that these two data points (i.e., Dr. Hunt's two patents cited by Patent Owner) are insufficient to demonstrate what is purportedly a "common" or "standard" level of disclosure in the field of herbicide patents.

In sum, we find that the challenged claims are extremely broad, the working examples are comparatively narrow, and the '202 patent fails to provide meaningful guidance as to how modifying each of the ten claimed variables—and particularly variables Q<sup>1</sup>, Q<sup>2</sup>, R<sup>1</sup>, and R<sup>6</sup>—would or would not impact herbicidal activity. Where, as here, "working examples are present but are 'very narrow, despite the wide breadth of the claims at issue,' this factor weighs against enablement." *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1161 (Fed. Cir. 2019) (quoting *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999)); *see also Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1348 (Fed. Cir. 2019) (working example was "insufficient to enable the breadth of the claims here, especially in light of the unpredictability of the art").

Accordingly, we find that the relatively narrow scope of working examples in the Specification weighs against enablement.

# e. Quantity of Experimentation

The scope of enablement encompasses not only what is disclosed in a patent's specification, but also what would be known to one of ordinary skill in the art without undue experimentation. *Nat'l Recovery Techs. Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195–96 (Fed Cir. 1999). "[T]he artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art." *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

Petitioner argues that "[g]iven the tremendous gap between the scope of the claims and the limited data in the patent, the testing needed to reliably predict the herbicidal activity of the full scope of the compounds claimed would be undue." Reply 2–3. Patent Owner argues that common modeling techniques (e.g., QSAR), together with the data in the Specification, permit an ordinarily skilled artisan to identify additional compounds for synthesis and screening for herbicidal activity. *See, e.g.*, Resp. 34 (citing Ex. 2011 ¶¶ 22–26, 51–57).

A QSAR model "is a type of regression model that seeks to establish the relationship between a predictor variable and a response." Ex. 2011 ¶ 23. Dr. Dayan explains that "the statistical description between the predictor and response variables is developed based on a set of training data, which can then be extended to predict features of new, but related, compounds." *Id.* Dr. Dayan asserts that "there is sufficient variation [in the

examples in the Specification] with respect to at least steric and electrostatic properties" to allow persons of ordinary skill in the art to use QSAR "to guide the synthesis and screening of additional molecules falling within the [claimed] genus." Ex. 2011 ¶ 51; see also id. ¶¶ 52–57. According to Patent Owner and Dr. Dayan, "[a] QSAR model can work in synergy with screening tests by focusing the compounds selected for screening, and subsequent QSAR models can then be constructed for optimizing lead candidates." Resp. 8 (citing Ex. 2011 ¶¶ 23–24; Ex. 2020, 213).

The record supports that as of the earliest possible filing date of the '202 patent, QSAR and field screening tests were among the tools ordinarily skilled artisans used during herbicide development. *See, e.g.*, Ex. 2011 ¶¶ 20, 26–28 (discussing common modeling and field screening tests); Ex. 1003 ¶ 39 (acknowledging use of screening tests in herbicide development); Ex. 2005, 488–89; Exs. 2017, 2022, 2024 (all relating to use of QSAR in herbicide development); *see also* Tr. 7:19–8:5 (Petitioner's counsel acknowledging that QSAR is used in the field). But on the facts of this case, we disagree with Patent Owner that the examples in the Specification include sufficient variation to permit a person of ordinary skill in the art to use QSAR and routine screening tests to identify additional compounds across the full scope of the claim without undue experimentation.

The record shows that QSAR's predictive scope is generally limited to compounds similar to those used to generate the model. Ex. 1029 ¶¶ 15–20. "The goal of QSAR is to develop models on a training set of compounds, these models will then allow for the prediction of the biological activity of related chemicals." Ex. 2018, 39. "[A] QSAR should not be used to make predictions that extrapolate outside of the area of knowledge of the training

set." *Id.* at 49; *see also* Ex. 1031, 195 ("[I]t is not typical and often not possible to specify accuracy and prediction confidence for individual unknown chemicals, specifically those unknown chemicals with structures requiring that the model extrapolate beyond the chemistry space determined by the training set."). In practice, this means, for example, that "if a QSAR is based on a set of compounds with a certain range of physico-chemical descriptors i.e. log P values, then it should not be used to make a prediction for a compound with a log P value outside of that range." Ex. 2018, 49.

Contrary to Dr. Dayan's suggestions (*see, e.g.*, Ex. 2011 ¶¶ 51–57), the range of steric and electrostatic properties represented by the substituents tested in the examples in the Specification is very limited compared to the broad range of steric and electrostatic properties encompassed by the remainder of the substituents recited in claim 1. *See supra* Section II.C.2.d. For example, the untested, claimed choices for R¹, R⁶, Q¹, and Q² significantly vary in size, electrostatic properties, and location of electron donating or withdrawing groups, such that a person of ordinary skill in the art would not agree that the few compounds tested adequately represent the steric and electrostatic properties of the full scope of the claimed range of substituents or compounds. Ex. 1029 ¶¶ 32–50.

Nor does Dr. Dayan demonstrate that sterics and electrostatics are the only two properties important for modeling the activity of the full scope of the claimed compounds. Other factors affect biological activity and can be used in modeling. *See, e.g.*, Ex. 1003 ¶¶ 142–46; Ex. 1029 ¶ 23 (listing physico-chemical properties that can be used in modeling), ¶ 24 (discussing importance of lipophilicity and the range seen across the claimed substituents), ¶ 30; Ex. 2018, 49 (discussing QSAR based on compounds

with a certain range of log P values); Reply 12–13. Indeed, Dr. Dayan concedes that most of the QSAR literature focuses not only on steric and electronic variation, but also on log P. Ex. 1028, 97:7–13. Yet he does not address the variety of log P values represented across the claimed genus or whether there is sufficient information in the Specification to model the same. Accordingly, we agree with Petitioner that any QSAR model created based on the biological data in the Specification would be limited in applicability compared to the full scope of claim 1. Ex. 1029 ¶¶ 17, 18, 40, 50; Reply 9–11.

Additionally, to make predictions, a QSAR model must be validated. Reply 11–12; see also, e.g., Ex. 1031, 198 ("[A] model's predictive capability minimally needs to be demonstrated using some sort of crossvalidation or external validation procedures."); Ex. 1034 at 4299 (Table 3, "External validation (by predicting unseen examples with the final QSAR equations) is the only way to establish a reliable QSAR model."); Ex. 2018 at 49 ("All predictive models require validation i.e. can they be used to make predictions."); Ex. 1029 ¶ 26. "When creating a QSAR, the available data is typically divided into a 'training' set, and a 'test data' set." Ex. 1029 ¶ 16. The training set is used to create the model, and the test data set is used for validation. *Id.*; Reply 10. Dr. Dayan testifies that all of the data in the Specification should be used in the training set (Ex. 1028 at 97:14–21), meaning that there is no data left for validation. Reply 12. Thus, Dr. Hunt explains that a person of ordinary skill in the art would "need to make and test a vast number of *different* compounds" just for the purpose of "verify[ing] that any model created could reliably predict activity across the

full scope of the claims," which further increases the amount of experimentation required. Ex. 1029 ¶ 54; see also id. ¶ 27; Reply 12.

The amount of experimentation necessary to practice the full scope of claim 1 is additionally compounded by the need for iterative modeling. Patent Owner asserts that "[a] QSAR model can work in synergy with screening tests by focusing the compounds selected for screening, and subsequent OSAR models can then be constructed for optimizing lead candidates." Resp. 8 (emphasis added) (citing Ex. 2011 ¶¶ 23–24; Ex. 2020, 213); see also Sur-reply 19–20 (quoting Ex. 2017, 516) ("[The] most useful predictions will often be those made for compounds lying near the edges of" the tested space, leading practitioners to employ "rolling test sets."). Each iteration includes modeling to identify candidates (including synthesizing compounds to create the test data set for validation), synthesizing promising candidate compounds identified in the modeling, and assaying those candidate compounds to assess herbicidal activity. Ex. 2011 ¶¶ 24, 51; Ex. 1029 ¶ 54; Reply 23. Petitioner establishes, and Patent Owner does not dispute, that synthesizing even a single claimed compound takes 7 or 8 days. Ex. 1003 ¶ 152. "This would make it time-consuming and burdensome for persons skilled in the art to try to create a broad range of compounds to test for activity," particularly if a person of ordinary skill in the art "sought to create widely varied structures in order to test the impact of substitutions at different groups." Id.; Pet. 21-22. Although neither party specifies the number of iterations that would be needed to reach the full scope of claim 1 (see, e.g., Ex. 1029 ¶ 51), the limited scope of data in the Specification and breadth of the claims suggests that many iterations would be necessary,

expanding the amount of work an ordinarily skilled artisan must carry out to practice the full scope of claim 1.

We acknowledge Federal Circuit precedent indicating that the test for undue experimentation is "not merely quantitative, since a considerable amount of experimentation is permissible." *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996); *see also Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1339 (Fed. Cir. 2013) ("[A] considerable amount of experimentation is permissible, if it is merely routine."); Resp. 12, 21–22. We also agree with Patent Owner that the quantity of experimentation needed is not viewed in the abstract, but as a function of the pertinent art. Resp. 21–22. Patent Owner argues that "extensive screening" of compounds is expected in the field, as are computational modeling techniques to assist with compound selection.

Resp. 24–25 (citing Ex. 2011 ¶¶ 10, 20; Ex. 1001, 155:17–156:13; Ex. 1003 ¶ 38; Pet. 11–12); *see also* Sur-reply 14–15 ("[I]t is within the knowledge of a person of ordinary skill in the art to explore related compounds by strategic substituent modifications.").

Although there is some support in the record for the notion that companies may synthesize and screen large numbers of compounds in the search for new herbicides (*see*, *e.g.*, Ex. 1019, 116–117), on this record we do not find that a general expectation of a high level of experimentation during herbicide development undercuts Petitioner's showing of undue experimentation. Rather, similar to *Idenix*, despite the high level of skill in the art and routine nature of synthesis and screening techniques, the "immense breadth of screening required to determine which [compounds] are effective [herbicides] can only be described as undue experimentation."

Idenix, 941 F.3d at 1162; see also Enzo Life Scis., Inc., 928 F.3d at 1348–49 (affirming lack of enablement where claims covered "tens of thousands" of polynucleotides, each of which would need to be tested to determine whether it had the claimed functionality); Wyeth, 720 F.3d at 1385 (affirming lack of enablement where "practicing the full scope of the claims would require synthesizing and screening each of at least tens of thousands of compounds").

Patent Owner relies on *Johns Hopkins Univ. v. CellPro, Inc.* (*see* Resp. 21–22), but that case is distinguishable. There, the prior art technique ("the Kohler/Milstein technique") taught in the specification to produce the claimed antibodies "was not foolproof" and "commonly required repetition," but expert testimony showed that this "lack of certainty was . . . not attributable to a failure of disclosure in the [subject] patent." *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998). Rather, the required experimentation stemmed from shortcomings with the prior art Kohler/Milstein technique for producing antibodies. Here, in contrast, the record shows that the required level of experimentation results from the limited guidance in the Specification as compared to the breadth of the claim, rather than from any shortcomings in known techniques available to ordinarily skilled artisans.

Patent Owner argues that our analysis suggests that "a skilled artisan would have to make and test every compound covered by the claims." Resp. 27. We do not so suggest. But the work a person of ordinary skill in the art would need to carry out is still undue. *See, e.g.*, Ex. 1029 ¶ 50. "Permissible experimentation is . . . not without bounds." *Cephalon*, 707 F.3d at 1339. For example, in *Idenix*, the claims recited a method of treating

HCV by administering nucleoside compounds having a specific chemical structure. *Idenix*, 941 F.3d at 1154. The *Idenix* court found that "at least many, many thousands" of potential compounds met the structural requirements of the claims, and their synthesis was routine. *Id.* at 1157, 1160. Nevertheless, each of the compounds "would need to be screened in order to know whether or not they are effective against HCV." *Id.* at 1162. The *Idenix* court stated that where "practicing the full scope of the claims would have required excessive experimentation, even if routine, the patent is invalid for lack of enablement." *Id.* at 1163 (citation omitted). Thus, in view of the quantity of experimentation required (even though the techniques were routine), the lack of meaningful guidance or working examples across the full scope of the claim, and the immense breadth of screening required to determine which claimed compounds are effective against HCV, the *Idenix* court found undue experimentation. *Id.* at 1162.

Patent Owner asserts *Idenix* is distinguishable because (1) there, the specification disclosed only four examples, whereas here, the working examples "include a wide range of different substituents reflecting different steric and electrostatic properties" (Resp. 63); (2) there, the field was "in its infancy" and there was no evidence of available modeling techniques that would "cut[] down on the number of compounds that a skilled artisan would actually need to synthesize and test" (*id.* at 49, 64); and (3) there, a skilled artisan would "need[] to randomly search a large group for the rare compound that would work" (*id.* at 65), but here, "the vast majority of the compounds covered by the claims of the '202 patent would have been expected to have herbicidal activity" (*id.* at 64).

Patent Owner's arguments are unavailing. First, the relative number of working examples in *Idenix* versus here does not persuasively distinguish *Idenix*. The claims in *Idenix* encompassed "at least many, many thousands" of candidate compounds, and the *Idenix* specification included four working examples. 941 F.3d at 1159, 1161. In contrast, the number of compounds within the scope of claim 1 here is vastly larger (encompassing more than a billion compounds), and the Specification includes working examples for only 335 compounds. Additionally, the variation in the working examples here is limited compared to the scope of the claims, and thus does not provide as much guidance as Patent Owner's argument suggests.

Second, the availability here of modeling techniques is likewise unavailing, because as discussed above, the facts of this case are such that QSAR cannot bridge the gap between the vast scope of claims and the comparatively limited disclosure in the Specification to enable persons of ordinary skill in the art to practice the full scope of the claim without undue experimentation. *See also* Reply 2–3 ("Given the tremendous gap between the scope of the claims and the limited data in the patent, the testing needed to reliably predict the herbicidal activity of the full scope of the compounds claimed would be undue.").

Finally, Patent Owner's suggestion that "the vast majority" of the claimed compounds here "would have been expected to have herbicidal activity" (Resp. 64) is not supported by credible analysis. Nor is Patent Owner's related suggestion that there are only a "small number" of inoperative embodiments within the scope of the claims. Resp. 19, 58–60 (citing, e.g., Ex. 2011 ¶¶ 59, 60). As support for these arguments, Patent Owner argues that "over 96% of the 335 tested compounds showed some

level of herbicidal activity, and that percentage would likely be higher at higher levels of application." *Id.* at 60. Patent Owner also relies on Dr. Dayan's testimony that based on the data in the Specification, "I would not expect that the number of inactive compounds would represent a significant portion of the claimed compounds." Ex. 2011 ¶ 59.

Patent Owner's reliance on a 96% activity rate is unavailing. The 335 compounds tested lack diversity and represent only a minuscule fraction of the claimed compounds. Ex. 1029 ¶ 7. Thus, there is no basis to extrapolate the 96% rate to the remainder of the compounds encompassed within the scope of claim 1 given the very different characteristics of the remaining claimed compounds. *Id.* ¶ 11. Further, Dr. Dayan's expectation that the claims embrace only a small number of inactive compounds is not supported with credible analysis. As discussed above, Dr. Dayan fails to appropriately grapple with the impact of the inactive compounds in the Specification in concluding that an ordinarily skilled artisan would expect few inactive compounds. See supra Section II.C.2.d. Dr. Dayan's opinion that if the inactive compounds were tested at higher concentrations they may exhibit herbicidal activity (Ex. 2011 ¶ 60) fares no better. We agree with Dr. Hunt that Dr. Dayan's assertion is mere speculation. Ex. 1029 ¶ 52. And although not dispositive, we also note that the tested concentrations (1000) and 500 g ai/ha) are "far above the normal concentrations used for commercial herbicides." *Id.*; see also Ex. 1003 ¶ 153.

Patent Owner likens this case to *Angstadt* (Resp. 59, 65–66), where the court found no basis to conclude that ordinarily skilled artisans, "armed with the specification and its 40 working examples, would not easily be able to determine which catalyst complexes within the scope of the claims work

to produce hydroperoxides and which do not." *In re Angstadt*, 537 F.2d 498, 503 (CCPA 1976). In *Angstadt*, however, the court found that skilled artisans would "easily" be able to determine whether complexes work. *Id.* Here, in contrast, extensive modeling, synthesis, and testing is needed to determine whether a given compound is operative. This case is further distinguished from *Angstadt* because there, the specification disclosed a "large but finite list" of catalysts to use in the claimed method. *Id.* at 503. Here, in contrast, it cannot be said that claim 1, which embraces at least one billion compounds, presents a "finite list" of options.

We find that the need for iterative QSAR modeling, together with the sheer number of candidate compositions that must be synthesized (each of which would take at least a week to make) for both the modeling and herbicide testing, weighs against enablement, especially in light of the limited guidance in the Specification and the general unpredictability in the art.

#### 3. Conclusion

In sum, it is undisputed that claim 1 covers at least a billion compounds. The art is unpredictable, and the Specification indicates that not all of the compounds falling within claim 1 are effective herbicides. *See*, *e.g.*, Pet. 22 (listing compounds that showed no herbicidal activity). Although the level of ordinary skill in the art is relatively high and the field is mature, Petitioner establishes by a preponderance of the evidence that the '202 patent does not provide sufficient meaningful guidance or working examples across the full scope of claim 1 to allow a person of ordinary skill in the art to determine which other compounds across the full scope of the claim have herbicidal activity without undue experimentation.

Claim 2 depends from claim 1 and narrows the recited choices for R<sup>9</sup> and R<sup>11</sup>. Ex. 1001, 288:14–15. Claim 3 depends from claim 2 and further narrows the recited choices for Y<sup>1</sup>, Y<sup>2</sup>, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, and R<sup>6</sup>. *Id.* at 288:16–20; Resp. 68; Ex. 2011 ¶ 63. The record does not reflect how many fewer compounds are encompassed by claims 2 and 3 as compared to claim 1. Nevertheless, neither claim 2 nor claim 3 directly narrows the substituents available at Q<sup>1</sup> and Q<sup>2</sup>, see Ex. 1003 ¶¶ 176–179, and there are "thousands of possible variations" at each of these positions. Ex. 1003 ¶ 159 n.8, ¶ 162 n.9. As such, given the breadth of claims 2 and 3, on this record we find that the same analysis for claim 1 applies to these claims. See also Pet. 30–31. Beyond pointing out how claim 3 limits certain positions (other than Q<sup>1</sup> and Q<sup>2</sup>), Patent Owner does not provide additional arguments specific to these claims. See Resp. 68; see also id. 67–68 ("For the same reasons described above as to claim 1 of the '202 patent, the remaining claims challenged by [Petitioner]—claims 2, 3, 9-13, and 21-30—are enabled.").

Claims 9–12 and 21 cover herbicidal compositions and mixtures. Ex. 1001, 288:61–289:30, 290:63–67. Claim 13 covers controlling vegetation growth using an "herbicidally effective amount" of a compound of claim 1. *Id.* at 289:31–35. None of claims 9–13 or 21 limit the breadth of compounds covered by claim 1, and thus, the same analysis for claim 1 applies equally to these claims. *See also* Pet. 30, 31. Patent Owner does not provide additional argument for these claims. *See* Resp. 67–68 ("For the same reasons described above as to claim 1 of the '202 patent, the remaining claims challenged by [Petitioner]—claims 2, 3, 9-13, and 21-30—are enabled.").

Claims 22–24 each depend from claim 1, and only limit the substituents available at Q<sup>1</sup>, without limiting Q<sup>2</sup>, R<sup>1</sup>, or R<sup>6</sup>. Ex. 1001, 291:1–19; Ex. 1003 ¶¶ 182–184. Claims 25–30 each depend from claim 1, and only limit the substituents available at Q<sup>2</sup>, without limiting Q<sup>1</sup>, R<sup>1</sup>, or R<sup>6</sup>. Ex. 1001, 291:20–292:44; Ex. 1003 ¶¶ 185–190. Because there are still "thousands of possible variations" at each of the remaining positions (Q<sup>2</sup>, R<sup>1</sup>, or R<sup>6</sup> as appropriate), on this record we find that the same analysis applied to claim 1 applies to these claims. *See*, *e.g.*, Ex. 1003 ¶¶ 139, 159 n.8, 162 n.9, 196; *see also* Pet. 31–32. Patent Owner does not provide additional argument for claims 22–30. *See* Resp. 68 ("For the same reasons that FMC has shown that the full scope of claim 1 is enabled, narrower claims 22–30 are also enabled.").

Accordingly, for the reasons discussed above, on the full trial record, we find that Petitioner has demonstrated by a preponderance of the evidence that challenged claims 1–3, 9–13, and 21–30 are unpatentable for lack of enablement.

# D. Written Description

The written description requirement, set forth in 35 U.S.C. § 112, requires that a patent's specification "contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). This provision ensures that "the inventor actually invented the invention claimed" and "had possession of the claimed subject matter as of the filing date." *Id.* at 1350–51. The test "requires an objective inquiry into

the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* at 1351.

On the full trial record, for the reasons discussed below, we determine that Petitioner has established by a preponderance of the evidence that claims 9–13 lack adequate written description support.

# 1. Brief Overview of the Parties' Contentions

Petitioner argues that the Specification does not provide adequate written description support for claims 9–13. Pet. 32. Claims 9–12 depend directly or indirectly from claim 1 and recite an herbicidal composition or mixture comprising a compound of claim 1, and claim 13 recites a method for controlling the growth of undesired vegetation comprising use of an herbicidally effective amount of a compound of claim 1. Ex. 1001, 288:61-289:35. Petitioner asserts that "[w]here, as here, the claims cover a broad genus, the disclosure must adequately reflect the structural diversity of the claimed genus, either through the disclosure of sufficient species that are 'representative of the full variety or scope of the genus,' or by the establishment of 'a reasonable structure-function correlation." Pet. 35 (quoting AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1300 (Fed. Cir. 2014)). Petitioner asserts that "[t]he same data that demonstrates that the patentee had not enabled use of the full scope of the compounds of claim 1 also demonstrates that it was not in possession of the full scope of the claimed inventions of claims 9–13." *Id.* at 36 (citing Ex. 1003 ¶ 201). Petitioner further asserts that "[t]he biological data fails to show herbicidal activity for the vast majority of the claimed compounds and in fact indicates that many claimed compounds showed no herbicidal activity." Id.

Patent Owner asserts that Petitioner's written description argument is "cursory," and that "the same disclosure that demonstrates enablement . . . also demonstrates written description." Resp. 69, 71. Patent Owner, relying on Dr. Dayan's testimony, argues that "a skilled artisan would understand that most of the compounds covered by the claims would have herbicidal activity." *Id.* at 71–72 (citing Ex. 2011 ¶¶ 59–60). Patent Owner also argues that the biological testing data for the 335 compounds in the Specification would have permitted a person of ordinary skill in the art reading the '202 patent "to recognize the relationship between the structure of the claimed compounds and herbicidal activity." *Id.* at 72 (citing Ex. 2011 ¶¶ 59–60).

## 2. Analysis

Each of challenged claims 9–13 requires herbicidal activity. Ex. 1001, 288:61–289:35. The pertinent question is whether the '202 patent demonstrates that the inventors were in possession of compounds, beyond those exemplified in the Specification, that fall within the claims and have herbicidal activity. *See, e.g., Idenix*, 941 F.3d at 1163. On this record, we determine that the Specification lacks sufficient disclosure to permit an ordinarily skilled artisan to conclude that the inventors were in possession of a genus of compounds having herbicidal activity as broad as claimed.

As discussed above, the '202 Specification does not adequately reflect the diversity of the claimed genus because the compounds for which herbicidal activity was demonstrated in the Specification are not representative of the full variety or scope of the genus. *See, e.g., supra* Section II.C.2.d; Ex. 1029 ¶¶ 23, 24, 30, 37–39; Ex. 1003 ¶¶ 142–46; Reply 23–24; *see also AbbVie Deutschland*, 759 F.3d at 1300 ("One needs to show

that one has truly invented the genus, *i.e.*, that one has conceived and described sufficient representative species encompassing the breadth of the genus."). Nor is there evidence of "a reasonable structure-function correlation." *AbbVie Deutschland*, 759 F.3d at 1301; *see also*, *e.g.*, Pet. 19–20; Ex. 1003 ¶ 150 ("A person reading the '202 Patent is left to guess how changing substituents outside of the limited examples provided will impact herbicidal efficacy."); ¶ 133 (asserting that the Specification "does not state what the intended mode of action is for the herbicidal use of the claimed compounds"); ¶ 146 ("Without knowing the mechanism by which the herbicide affects plant growth, a POSA has little ability to predict how changes on the structure of a molecule can impact biological activity."); ¶ 147 (asserting that the examples in the Specification "do not provide sufficient guidance for a POSA to determine which of billions of compounds claimed would be effective as an herbicide"); *supra* Section II.C.2.c.

Patent Owner relies on Dr. Dayan's testimony that "a skilled artisan would understand that most of the compounds covered by the claims would have herbicidal activity" (Resp. 71), but as discussed above, Dr. Dayan's testimony on this point is conclusory. *See supra* Section II.C.2.e. Patent Owner also asserts that the 335 compounds tested in the Specification "would have provided significant guidance to a skilled artisan, especially in conjunction with the modeling that is commonly used in the art," such that a person of ordinary skill "reading the '202 patent would have been able to recognize the relationship between the structure of the claimed compounds and herbicidal activity." Resp. 72 (citing Ex. 2011 ¶¶ 59, 60). But Patent Owner and Dr. Dayan fail to explain what in the Specification would permit an ordinarily skilled artisan to divine a relationship between structure and

activity, given that the test data is clustered around a narrow range of structures compared to the remaining scope of claimed structures, and given that what little testing deviates from this cluster shows diminishing activity. See, e.g., Ex. 1029 ¶¶ 11–12; Ex. 1003 ¶¶ 163–72; Reply 7. Thus, similar to *Idenix*, based on the Specification a person of ordinary skill in the art "is deprived of any meaningful guidance into what compounds beyond the examples and formulas, if any, would provide the same result," and "[i]n the absence of that guidance, the listed examples and formulas cannot provide adequate written description support for undisclosed" compounds that also have herbicidal effect. *Idenix*, 941 F.3d at 1164.

Accordingly, we conclude that Petitioner has established by a preponderance of the evidence that claims 9–13 lack adequate written description support.

## E. Anticipation

Petitioner asserts that claims 1–7 and 22–31 are unpatentable under 35 U.S.C. § 102(a)(1) as anticipated by Olsson (Ex. 1004). Pet. 36. "To anticipate, the reference must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements arranged as in the claim." *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083 (Fed. Cir. 2008) (internal quotation omitted). In other words, it is not enough to be able to find all of the pieces of the claimed invention somewhere in a prior art reference; rather, those elements must be set out in the prior art reference in the same way they are in the claimed invention. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) ("Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only

disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'") (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)).

On the full trial record, we determine that Petitioner has not established by a preponderance of the evidence that claims 1–7 and 22–31 are unpatentable under 35 U.S.C. § 102(a)(1) as anticipated by Olsson.

We first provide an overview of Olsson and the parties' contentions, then present our analysis.

## 1. Overview of Olsson (Ex. 1004)

Olsson, titled "PAR2-Modulating Compounds and Their Use," "relates to compounds that modulate the activity of proteinase-activated receptor-2 (PAR2), to the use of the compounds as tools for the further elucidation of the role of PAR2 in biological systems and to the treatment and prevention of diseases and disorders related to PAR-2." Ex. 1004, code (54), ¶ 2. Olsson states that PAR2 receptors have been implicated in numerous physiological processes, and lists treatment applications for the disclosed compounds. *Id.* ¶¶ 5, 32–64, 185.

Olsson discloses a genus of compounds having the core structure reproduced below:

$$R_1$$
 $R_{1n}$ 
 $R_{2n}$ 

Id.  $\P$  7. The structure reproduced above depicts the core structure of Olsson's compounds, which comprises a pyrrolidinone ring. Olsson

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discloses various choices for the substituents on this core structure, and exemplifies several specific compounds. *See, e.g., id.* ¶¶ 8–31, 65–128. Olsson provides synthetic routes for making the compounds, and discloses "a method for treating or preventing a disease or disorder related to abnormal PAR2 activity comprising administering a therapeutically effective amount of one or more of the compounds." *Id.* ¶¶ 129, 184.

# 2. Brief Overview of the Parties' Contentions

Formula I recited in claim 1 of the challenged patent is reproduced below:

$$\mathbb{R}^3$$
 $\mathbb{R}^4$ 
 $\mathbb{R}^5$ 
 $\mathbb{R}^6$ 
 $\mathbb{R}^6$ 

Ex. 1001, 285:31–41. Formula I above depicts the core structure recited in claim 1 of the challenged patent. Petitioner argues that when R<sup>2</sup>, R<sup>3</sup>, and R<sup>4</sup> are hydrogen, and Y<sup>1</sup> and Y<sup>2</sup> are oxygen, the structure of formula I of challenged claim 1 becomes the structure reproduced below:

$$Q^1$$
 $R^5$ 
 $R^6$ 

Pet. 38–39 (citing Ex. 1003 ¶ 82). The structure above depicts the core structure of claim 1, where R², R³, and R⁴ are hydrogen, and Y¹ and Y² are oxygen. Petitioner argues that "[t]his is the same core as of Olsson (described in paragraph 7), when (n) is set to 1 (as disclosed in paragraph 8, and as illustrated in paragraph 7), and R₃ is selected as —NR₅bR₅c, which is one of the three options identified in paragraph 15, and in Olsson's claim 2." *Id.* at 39 (citing Ex. 1004 ¶¶ 7, 8, 15, 184; Ex. 1003 ¶ 83). Petitioner provides a depiction of Olsson's core structure with these substitutions, which we reproduce below:

$$R_1$$
 $R_{1a}$ 
 $R_{5c}$ 
 $R_{1b}$ 
 $R_{5c}$ 

*Id.* at 39. The structure above depicts Olsson's core structure, with (n) set to 1 and  $R_3$  selected as —NR<sub>5b</sub>R<sub>5c</sub>. Petitioner also provides the following sideby-side comparison:

*when: R <sup>2</sup> , R <sup>3</sup> , and R <sup>4</sup> are H, Y <sup>1</sup> and Y <sup>2</sup> are O	*when: n is 1 and R <sub>3</sub> is —NR <sub>5b</sub> R <sub>5c</sub>
$Q^1$ $R^5$ $R^6$ $R^6$	$R_{1a}$ $R_{5b}$ $R_{1a}$ $R_{5c}$

*Id.* at 40. The comparison above depicts Formula I of the '202 patent with the above-described substitutions (shown on the left), and Olsson's core structure with the above-described substitutions (shown on the right).

Petitioner further argues that  $R_1$  in Olsson corresponds to the  $Q^1$  group in claim 1 of the '202 patent, and that for  $R_1$ , Olsson describes "[o]ptionally substituted aryls and heteroaryls [as] the first choices," where aryls are defined to include benzene rings. Pet. 41–42 (citing Olsson ¶¶ 25, 133). Petitioner further argues that "a benzene ring attached to a carbon atom at the  $R^1$  position of Olsson<sup>[11]</sup> would be a phenyl group," and "a POSA would understand and be able to envisage that Olsson describes the phenyl group of  $Q^1$ ." *Id.* at 42 (citing Ex. 1003 ¶ 88); *see also id.* at 42–43 (arguing that based on other choices for  $R_1$  disclosed in Olsson, an ordinarily skilled artisan could visualize other substituents defined in the '202 patent for  $Q^1$ ).

convention.

<sup>&</sup>lt;sup>11</sup> Although Petitioner sometimes uses superscripts when referring to positions on Olsson's core (*see, e.g.*, Pet. 41, referencing Olsson's "R<sup>1</sup>" group), Olsson uses subscripts (*see, e.g.*, Ex. 1004 ¶ 7, referencing "R<sub>1</sub>"). For clarity, except when quoting Petitioner or Dr. Hunt, we use Olsson's

As will be discussed further below, Petitioner makes similar arguments that Olsson defines other substituents on its core structure that overlap with substituents that are defined for Formula I in challenged claim 1. *See id.* at 43–46 (discussing the Q<sup>2</sup> position in challenged claim 1), 47 (discussing the R<sup>1</sup>, R<sup>5</sup>, and R<sup>6</sup> positions in challenged claim 1); *see also id.* at 49–68 (claim chart comparing the limitations of challenged claim 1 with Olsson's disclosures).

Patent Owner argues that Petitioner does not "identify any embodiment of Olsson that falls within the challenged claims," and that Petitioner's anticipation argument instead "relies on picking and choosing unrelated disclosures from disparate and unconnected aspects of the Olsson reference." Resp. 74–75.

## 3. Analysis

We agree with Patent Owner that Petitioner has not directed us to any species compound in Olsson that falls within the scope of the challenged claims. Resp. 74. Instead, we find that Petitioner "relies on picking and choosing unrelated disclosures from disparate and unconnected aspects of the Olsson reference," without identifying teachings in Olsson that direct an ordinarily skilled artisan to make all of the necessary choices simultaneously. *Id.* at 74–75.

First, while Olsson's core structure allows for either a 5-, 6-, or 7-membered ring, Petitioner focuses on a 5-membered ring. Ex. 1004 ¶¶ 7, 8; Pet. 39. Petitioner does point us to a reason to focus on 5-membered rings, noting that Olsson describes such rings in seven of its eight syntheses schemes. Pet. 39 (citing Ex. 1004 ¶ 184; Ex. 1003 ¶ 83 (noting that "a 5

membered ring (e.g., n=1) is the configuration that Olsson depicts in most of its syntheses schemes (schemes 2-8)")).

Second, from among the options Olsson specifies for the  $R_3$  position, Petitioner selects an amine functional group,  $NR_{5b}R_{5c}$ . Pet. 39. Petitioner asserts that where  $R_3$  is  $NR_{5b}R_{5c}$ ,  $R_{5b}$  and  $R_{5c}$  respectively correspond to the  $Q^2$  and  $R^6$  positions recited in claim 1 of the '202 patent. *Id.* at 41 (table), 43. Although Petitioner asserts that  $NR_{5b}R_{5c}$  "is one of the three options identified in [Olsson's] paragraph 15, and in Olsson's claim 2" (*id.*), this rationale fails to account for the multitude of other options for  $R_3$  disclosed elsewhere in Olsson. *See* Ex. 1004 ¶¶ 12, 19, 26. That said, Petitioner also points us to Olsson's Scheme 3, which depicts a core having a 5-membered ring, where  $R_3$  is  $NR_{5b}R_{5c}$ , and more specifically, where  $R_{5b}$  is a substituted phenyl ring and  $R_{5c}$  is hydrogen. Pet. 40–41 (citing Ex. 1004 ¶ 184; Ex. 1003 ¶¶ 83–84). Petitioner notes that Olsson also separately provides that  $R_{5b}$  may be, among other things, an aryl ring. *Id.* at 43; Ex. 1004 ¶ 18.

Third, Petitioner asserts that "Olsson's R<sup>1</sup> position corresponds to the '202 patent's Q<sup>1</sup>," and that Olsson describes aryl groups (which Petitioner asserts includes phenyl rings) among the first choices for R<sub>1</sub>. *Id.* at Pet. 41–42 (citing Ex. 1004 ¶¶ 25, 133; Ex. 1003 ¶ 88). Petitioner also notes that synthesis schemes 7 and 8 depict a substituted phenyl group at the position corresponding to Q<sup>1</sup>. *Id.* at 42 (citing Ex. 1004 ¶ 184).

Fourth and finally, with regard to the  $R^1$ ,  $R^5$ , and  $R^6$  positions of the '202 patent, which Petitioner asserts respectively correspond to the  $R_2$ ,  $R_{1a}$ , and  $R_{5c}$  (or  $R_{4a}$ ) positions of Olsson (*see* Pet. 41, 47), Petitioner asserts for example that "Olsson discloses that any of the R positions may be H, a

halogen or a  $C_1$ - $C_4$  alkyl, which falls within the scope of  $R^1$ ,  $R^5$ , and  $R^6$  in claim 1." *Id.* at 47 (citing Ex. 1004 ¶ 130; Ex. 1003 ¶ 101).

Petitioner directs us to information tending to show that individual substituents of the genus recited in challenged claim 1 can be found within Olsson's disclosure, as outlined above. However, Petitioner's presentation lacks, for example, any rationale as to how Olsson teaches making each of these disparate choices simultaneously. To establish anticipation, a "reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972). On this record, we find that Petitioner has not met this standard.

Petitioner's arguments for the remaining challenged claims suffer from the same flaws. Each of challenged dependent claims 2–7 and 22–30 narrows the choice of substituents at one or more positions of the generic formula recited in challenged claim 1. *See* Ex. 1001, 288:14–48, 291:1–292:44. Independent claim 31 recites the same core compound as claim 1, but as compared to claim 1, recites fewer options for R<sup>2</sup>–R<sup>6</sup>, Q<sup>1</sup>, Q<sup>2</sup>, Y<sup>1</sup>, and Y<sup>2</sup>. *Id.* at 292:45–293:24. Petitioner points us to where in Olsson the claimed options are individually taught, but once again, does not demonstrate that Olsson clearly and unequivocally discloses a compound

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<sup>&</sup>lt;sup>12</sup> Petitioner additionally outlines where in Olsson's disclosure the optional substituents recited in challenged claim 1 are purportedly found. *See, e.g.*, Pet. 45–47. Because the optional substituents are not necessary to anticipate challenged claim 1, we need not address them here.

falling within the scope of the challenged claims, or that Olsson directs ordinarily skilled artisans to the claimed compounds without any need for picking or choosing. *See* Pet. 69–90.

We identified these same shortcomings in Petitioner's arguments in the Institution Decision (*see* Inst. Dec. 44–48), but Petitioner did not further address anticipation during trial. *See generally* Reply.

For the above reasons, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–7 and 22–31 are unpatentable as anticipated by Olsson.

#### F. Obviousness

Petitioner asserts that claims 1–7 and 22–31 are unpatentable as obvious over Olsson. Pet. 90. Petitioner reiterates that Olsson discloses "each and every limitation" of claims 1–7 and 22–31. *Id.* Petitioner argues that "it may be obvious to a person of ordinary skill in the art to try a combination of elements where there are a finite number of identifiable solutions and a good reason to pursue the technical solutions within their grasp," and "Olsson explains that there was strong interest in modifying the compounds it discloses because of their applicability to the PAR2 enzyme, which was known to have wide applicability in treating a wide range of physiological conditions." *Id.* at 92–93.

Patent Owner responds that Olsson "posits a large number of options for each of the functional groups, [which] cuts against a finding of obviousness." Resp. 76.

We agree with Patent Owner. Petitioner relies on an "obvious to try" theory. Pet. 92–93. In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007), the Supreme Court explained that a combination of elements

may be "obvious to try" when there is a design need or market pressure and an artisan of ordinary skill in the art pursues known options from "a finite number of identified, predictable solutions." The Federal Circuit "has elaborated that the identified path must 'present a finite (and small in the context of the art) number of options easily traversed to show obviousness." *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc., USA*, 748 F.3d 1354, 1360 (Fed. Cir. 2014) (quoting *Ortho–McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008)).

On the full trial record, we determine that Petitioner has not demonstrated that this is a situation with a "finite" or "small or easily traversed[] number of options that would convince an ordinarily skilled artisan of obviousness." Ortho-McNeil Pharm., 520 F.3d at 1364. Petitioner points to several selections that must be made from Olsson's disclosure to result in a compound that falls within the scope of the challenged claims, where each selection is chosen from a sizeable menu of possible options. See Pet. 91–93 (discussing, for example, selection of a 5membered ring core, and choices for, at a minimum, substituents R<sub>3</sub>, -R<sub>5b</sub>, -R<sub>1a</sub>, -R<sub>5c</sub>, R<sub>1</sub>, and R<sub>2</sub> on this core); see also id. (acknowledging that "Olsson describes numerous options that satisfy each of the limitations (a)-(f) at the end of claim 1"). But Petitioner has not put forth a rationale as to how Olsson teaches making each of these disparate choices simultaneously in a manner that reaches the claimed compounds. Rather, in focusing on the chosen substituents, it appears that Petitioner "uses the claimed compounds of the '202 patent to guide it through the disclosure of Olsson." Resp. 77. This is classic impermissible hindsight. Cf. Grain Processing Corp. v. Am. Maize-Products Co., 840 F.2d 902, 907 (Fed. Cir. 1988) ("Care must be

taken to avoid hindsight reconstruction by using 'the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.") (quoting *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983)).

We identified these same shortcomings in Petitioner's arguments in the Institution Decision (*see* Inst. Dec. 44–48), but Petitioner did not further address obviousness during trial. *See generally* Reply.

Accordingly, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–7 and 22–31 are unpatentable as obvious over Olsson.

### III. PETITIONER'S MOTIONS TO EXCLUDE

A. Petitioner's Motion to Exclude Dr. Dayan's Testimony

Pursuant to Federal Rules of Evidence ("FRE") 402, 403, and 702, Petitioner moves to exclude Dr. Dayan's testimony that (1) a person of ordinary skill in the art would expect herbicidal activity from the majority of the claimed compounds; (2) QSAR modeling would allow a person of ordinary skill in the art to reliably predict the herbicidal activity of the full scope of claimed compounds; and (3) any additional testing required to enable the '202 patent would be "routine." Paper 24, 1. Petitioner argues that this testimony is inadmissible because it applies the incorrect legal standard for enablement and is conclusory, unreliable, and contrary to the evidence and therefore prejudicial. *Id.* at 4–5, 14.

Patent Owner responds that Petitioner's motion is an unauthorized reply to Patent Owner's Sur-reply because it simply re-argues issues on the

merits. Paper 27, 1. Patent Owner also argues that Dr. Dayan's testimony is relevant and well-supported by scientific literature. *Id.* at 3.

Petitioner, as the moving party, bears the burden of establishing that it is entitled to the requested relief. 37 C.F.R. §§ 42.20(c), 42.62(a). We determine that Petitioner has not met its burden. The arguments raised in Petitioner's motion relate to the sufficiency, rather than admissibility, of evidence. Such arguments are improperly advanced in a motion to exclude. See Patent Trial and Appeal Board Consolidated Trial Practice Guide (November 2019)<sup>13</sup> at 79 (stating that a motion to exclude may not be used to challenge the sufficiency of the evidence to prove a particular fact); see also Corning Inc. v. DSM IP Assets B.V., IPR2013-00053, Paper 66 at 19 (PTAB May 1, 2014) ("[T]he Board, sitting as a non-jury tribunal, is wellpositioned to determine and assign appropriate weight to the evidence presented in this trial."). Moreover, "there is a strong public policy for making all information filed in an administrative proceeding available to the public." Liberty Mut. Ins. Co. v. Progressive Cas. Ins. Co., CBM2012-00010, Paper 59 at 40 (PTAB Feb. 24, 2014). Rather than excluding evidence that is allegedly conclusory or contrary to the evidence, we simply give it the appropriate weight in our analysis.

We deny Petitioner's motion to exclude Dr. Dayan's testimony.

B. Petitioner's Motion to Exclude Dr. Hunt's Patents

During Dr. Hunt's deposition, Patent Owner introduced two patents listing Dr. Hunt as an inventor. Paper 25, 1. Petitioner moves to exclude

<sup>&</sup>lt;sup>13</sup> Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

testimony, exhibits, and arguments regarding these patents under FRE 401, 402, and 403 as irrelevant, prejudicial, and confusing the issues. *Id.* at 3.

Patent Owner responds that Dr. Hunt's patents are relevant to show the general practice in the field, to highlight the improperly heightened standards to which Petitioner allegedly subjects the '202 patent, and to call into question the credibility of Dr. Hunt's opinions. Paper 26, 4.

Dr. Hunt's patents relate to his own inventions, and Patent Owner was justified in cross examining Dr. Hunt on alleged inconsistencies between disclosure in his patents and his opinions here. The patents are thus relevant to at least Dr. Hunt's credibility, and we are unpersuaded that the probative value of the patents to our weighing of Dr. Hunt's testimony is substantially outweighed by potential prejudice or confusion of issues. As discussed above, the Board is well-positioned to determine and assign appropriate weight to the presented evidence, and there is a strong public policy for making all information filed in an administrative proceeding available to the public.

Accordingly, we deny Petitioner's motion to exclude testimony, exhibits, and arguments regarding Dr. Hunt's patents.

### IV. CONCLUSION<sup>14</sup>

Based on the information presented, we conclude that:

(1) Petitioner has shown by a preponderance of the evidence that claims 1–3, 9–13, and 21–30 are unpatentable under 35 U.S.C. § 112(a) for lack of enablement;

<sup>&</sup>lt;sup>14</sup> Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice* 

- (2) Petitioner has shown by a preponderance of the evidence that claims 9–13 are unpatentable under 35 U.S.C. § 112(a) for lack of adequate written description;
- (3) Petitioner has not shown by a preponderance of the evidence that claims 1–7 and 22–31 are unpatentable under 35 U.S.C. § 102(a)(1) as anticipated by Olsson; and
- (4) Petitioner has not shown by a preponderance of the evidence that claims 1–7 and 22–31 are unpatentable under 35 U.S.C. § 103 as obvious over Olsson.

## In summary:

Claims	35	Reference(s)/Basis	Claims	Claims
	U.S.C. §		Shown	Not shown
			Unpatentable	Unpatentable
1–3, 9–	112	Enablement	1–3, 9–13,	
13, 21–			21–30	
30				
9–13	112	Written	9–13	
		Description		
1–7, 22–	102	Olsson		1-7, 22-31
31				
1–7, 22–	103	Olsson		1-7, 22-31
31				
Overall			1-3, 9-13,	4–7, 31
Outcome			21–30	

Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

#### V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–3, 9–13, and 21–30 of U.S. Patent 10,294,202 B2 have been shown by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that claims 4–7 and 31 of U.S. Patent 10,294,202 B2 have not been shown by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that Petitioner's Motions to Exclude are *denied*; and

FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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