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POLSINELLI PC
900 WEST 48TH PLACE
SUITE 900
KANSAS CITY, MO 64112-1895

EXAMINER
HUTSON, RICHARD G

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DUNCAN ROY CLARK, MARTIN WILKINSON, and NICHOLAS MORANT[1]

Appeal 2017-010019
Application 12/812,519
Technology Center 1600

Before FRANCISCO C. PRATS, MICHAEL J. FITZPATRICK, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision under 35 U.S.C. § 134(a) involving claims directed to a chimeric protein. Claims 1, 6, 9, 11, 14, 18, 23, and 28 are on appeal as rejected under 35 U.S.C. § 112, first paragraph, and § 103. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] Appellants identify the Real Party in Interest as "Genesys Biotech Ltd." Appeal Br. 3. Herein we reference the Specification of July 12, 2010 ("Spec."); Final Office Action of Sept. 26, 2016 ("Final Action"); Appeal Brief of Feb. 21, 2017 ("Appeal Br."); Examiner's Answer of May 17, 2017 ("Answer"); and Reply Brief of July 17, 2017 ("Reply Br.").

STATEMENT OF THE CASE

Independent claim 1 is representative and is reproduced below:

> 1. A chimeric protein comprising a DNA polymerase domain having DNA polymerase activity joined with a Cren7 enhancer domain having at least 35% sequence identity with the amino acid sequence of SEQ ID NO:1, wherein the Cren7 enhancer domain enhances the activity of the DNA polymerase domain compared with a corresponding protein lacking the Cren7 enhancer domain.

Appeal Br. 16 (Claims Appendix).

The following rejections are appealed:

Claims 1, 6, 8, 9, 11, 13, 18, 23, and 28 stand rejected under 35 U.S.C. § 112, first paragraph, as failing under the written description requirement. Final Action 3.

Claims 1, 6, 8, 9, 11, 13, 18, 23, and 28 stand rejected under 35 U.S.C. § 103(a) over Guo[2] and Wang[3]. *Id.* at 5.

DISCUSSION

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Arguments made by Appellants in the Appeal Brief and properly presented in the Reply Brief have been considered in this Decision; arguments not so-

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[2] Li Guo et al., *Biochemical and Structural Characterization of Cren7, A Novel Chromatin Protein Conserved Among Crenarchaea*, 36 NUCLEIC ACIDS RES. 1129–37 (2008) ("Guo").

[3] Yan Wang et al., *A Novel Strategy to Engineer DNA Polymerases for Enhanced Processivity and Improved Performance in vitro*, 32 NUCLEIC ACIDS RES. 1197–207 (2004) ("Wang").

presented in the Briefs are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015); *see also Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative) ("Any bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived.").

I. WRITTEN DESCRIPTION

The Examiner determined that the claims' scope encompasses Cren7 enhancer domains having as little as "35% sequence identity with the amino acid sequence of SEQ ID NO:1" and, although the Specification discloses some examples within this scope, it

> does not provide a single representative species of that chimeric protein, encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification fails to describe any representative species of these chimeric proteins comprising a DNA polymerase domain having DNA polymerase activity joined with a Cren7 enhancer domain having a mere 35% sequence identity with the amino acid sequence of SEQ ID NO:1, wherein the Cren7 enhancer domain enhances the activity of the DNA polymerase domain compared with a corresponding protein lacking the Cren7 enhancer domain and wherein, when the DNA polymerase domain is a thermostable DNA polymerase by any identifying structural characteristics or properties, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Final Action 4.

Appellants' Appeal Brief wholly ignores this rejection. *See generally* Appeal Brief; *see, e.g., id.* at 4 ("**GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**" lists only the § 103 rejection). Appellants attempt

to revive an argument over this rejection in their Reply Brief; however, this argument is not timely and is not considered. Appellants present no showing of good cause why the argument was not presented in the Appeal Brief and could not be presented until the Reply Brief. The Examiner has had no opportunity to respond to any points made in the Reply Brief on record in this appeal. An argument raised for the first time in a Reply Brief can be considered waived if Appellants do not explain why it could not have been raised previously. *See Ex parte Nakashima*, 93 USPQ2d 1834, 1837 (BPAI 2010) (informative) (explaining that arguments and evidence not timely presented in the principal Brief will not be considered when filed in a Reply Brief, absent a showing of good cause explaining why the argument could not have been presented in the Principal Brief); *Ex parte Borden*, 93 USPQ2d at 1477.

Under 35 U.S.C. § 112, first paragraph, a "sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc) (citation omitted). When considering whether representative species have been disclosed,

> [o]ne factor in considering the question is how large a genus is involved and what species of the genus are described in the patent. If the genus is not large or, even if it is, [and] the specification discloses species representing the genus throughout its scope, the requirement may be met. On the other hand, analogizing the genus to a plot of land, if the disclosed species only abide in a corner of the genus, one has not described the

> genus sufficiently to show that the inventor invented, or had possession of, the genus. He only described a portion of it.

AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1285, 1299–1300 (Fed. Cir. 2014). "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. Otherwise, one has only a research plan, leaving it to others to explore the unknown contours of the claimed genus." *Id.* at 1300.

Under our reviewing court's precedent, the Examiner's rejection for lack of written description has merit. Appellants' Specification does not identify sufficient representative examples within the scope of the claims, i.e., *at least 35%* sequence identity with SEQ ID NO:1. Further, the Specification does not identify what structural features common to the members of the genus matter when one desires a Cren7 domain to function properly in the chimeric protein. Moreover, the Specification has not identified an example of a chimeric protein having a Cren7 domain with as little as 35% sequence identify with SEQ ID NO:1. Returning to the plot of land analogy set forth by our reviewing court, the Specification does not inform the skilled artisan where to precisely lay the fence, much less all that should be considered to reside within its bounds.

For the reasons above, we affirm this rejection.

II. OBVIOUSNESS

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). "[W]hen a patent claims a structure already known in the prior art that is altered by the mere

substitution of one element for another known in the field, the combination must do more than yield a predictable result." *Id.* at 416 (citing *U.S. v. Adams*, 383 U.S. 39, 50–51 (1966)). "In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *Id.* at 419. "[C]ase law is clear that obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) (citing *In re Corkill*, 771 F.2d 1496, 1500 (Fed. Cir. 1985)).

> [M]otivation to combine is . . . inextricably linked to the level of ordinary skill. . . . If the level of skill is low, . . . then it may be rational to assume that such an artisan would not think to combine references absent explicit direction in a prior art reference. If, however, . . . the level of skill is . . . [high], then one can assume comfortably that such an artisan will draw ideas from chemistry and systems engineering—without being told to do so.

Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1370 (Fed. Cir. 2006). "[T]he question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination, not whether there is something in the prior art as a whole to suggest that the combination is the most desirable combination available." *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (citation omitted).

> One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of "unexpected results," *i.e.*, to show that the claimed invention exhibits some superior

> property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.

In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995). "For objective evidence [of nonobviousness] to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention." *In re GPAC, Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995).

"The evidence presented to rebut a *prima facie* case of obviousness must be commensurate in scope with the claims to which it pertains." *In re Dill*, 604 F.2d 1356, 1361 (CCPA 1979). "[C]ommensurate in scope" means that the evidence provides a reasonable basis for concluding that the untested embodiments encompassed by the claims would behave in the same manner as the tested embodiment(s). *See In re Lindner*, 457 F.2d 506, 508 (CCPA 1972) ("Here, only one mixture of ingredients was tested. . . . The claims, however, are much broader in scope, . . . and we have to agree with the Patent Office that there is no 'adequate basis for reasonably concluding that the great number and variety of compositions included by the claims would behave in the same manner as the [single] tested composition.'") (citation omitted) (bracketed material in original).

The Examiner determined the claims would have been obvious over Guo and Wang, combined. Final Action 5–13 and Answer 5–17 (collectively citing Guo generally, but specifically at 1132, 1134, figures 1, 4B, 4C, 5; and Wang generally). We discern no error in the Examiner's determinations and adopt the Examiner's findings of fact and rationale. Final Action 5–13; Answer 5–17.

Before addressing Appellants' arguments, we note Appellants do not dispute that the Cren7 protein disclosed by Guo meets the Cren7 enhancer

domain element of the claims. Further, Appellants do not dispute that Wang's DNA polymerase component of Wang's disclosed Sso7d-DNA polymerase complex meets the DNA polymerase domain element of the claims. Further, Appellants do not dispute that Guo's comparisons of Cren7 with Sac7d protein are also relevant to and informative on respective similarities between Cren7 and the Sso7d protein disclosed by Wang. Further, Appellants do not dispute that there was no technological barrier to substituting the Sso7d domain of Wang's complex with Guo's disclosed Cren7 protein or that the subsequent Cren7-DNA polymerase complex would be the chimeric protein of claim 1. Each of these points of fact are relevant to the Examiner's rationale in combining Guo and Wang and we conclude each is established and uncontested. Even if Appellants dispute these points, they present no specific evidence thereon in this appeal.

What Appellants contest on Appeal is the propriety of substituting Wang's Sso7d protein with Guo's Cren7 protein based on the disclosures of the Guo and Wang references — Appellants argue the Examiner has not established that the references provide a good reason to make such a substitution. *See generally* Appeal Br. 4–15. We do not find this argument persuasive. In view of our reviewing court's precedent on this issue, we conclude it is undeniable that the level of ordinary skill in the relevant field would be high and, thus "an artisan . . . [would have] draw[n] ideas from chemistry and systems engineering—without being told to do so." *Dystar*, 464 F.3d at 1370.

We address Appellants' specific arguments below, but note at the outset that Wang describes the advantages of complexing a DNA binding

protein, specifically Sso7d, with DNA polymerase to improve processivity of the polymerase (e.g., during PCR); "**the dsDNA binding property of Sso7d is essential for the enhancement**." Wang 1197. Wang describes the enhancement in processivity by Sso7d as due to its "'mechanically' preventing the polymerase from dissociating from its DNA template," i.e., the protein physically holds the dsDNA. *Id.* at 1205. Wang identifies the properties of a dsDNA binding protein desired for such a complex: the protein "must be thermostable and bind to dsDNA without sequence preference." *Id.* at 1200. Wang characterizes Sso7d as a protein falling within this category. Wang also indicates that "[d]ue to its small size and high thermal stability . . . , Sso7d is unlikely to perturb the structural integrity of a fusion partner." *Id.* at 1204. Finally, Wang's concluding point is that "other types of dsDNA binding proteins in place of Sso7d is an interesting possibility that remains to be explored," thus expressly soliciting attempts at using other, similar proteins in such a DNA polymerase complex. *Id.* at 1205.

Guo identifies and characterizes just such a similar dsDNA-binding protein, i.e., Cren7. *See generally* Guo. Guo indicates that Cren7 is a dsDNA binding protein with little sequence specificity in DNA binding and is thermostable; even "significantly increas[ing] the stability of dsDNA against thermal denaturation." *Id.* at 1132. Guo also indicates that Cren7 is "small," which Wang indicates is attractive so as not to perturb its fusion partner. *Id.* at 1129. Thus, Guo teaches that Cren7 meets the properties Wang indicates as desired in selecting a DNA polymerase-complexing dsDNA binding protein.

Further, as identified by the Examiner, Cren7 is "a small, basic and methylated protein capable of efficient binding to dsDNA and constraining negatively DNA supercoils." *Id.* at 1133. Thus, Guo indicates that Cren7, like Sso7d disclosed by Wang, is small so as not to perturb the DNA polymerase and mechanically holds dsDNA. Further, Guo identifies significant structural similarities between Cren7 and Sac7d (and, thus, Sso7d); and while Guo also indicates that there are also differences, as noted, it is described as generally functioning similarly in constraining DNA, which is the role of Sso7d in Wang. *See id.* at 1134–35. Guo even indicates that "Cren7 is about twice as efficient as, but otherwise resembles, Sul7d [and so, also Sac7d and Sso7d,] in constraining DNA supercoils." *Id.* at 1133, 1136.

Taking the two prior art references as a whole, we conclude, in agreement with the Examiner's determinations, that Wang discloses complexing a dsDNA binding protein, such as Sso7d, with a DNA polymerase enhances the polymerase's processivity. Further, in response to Wang's explicit invitation to substitute some other dsDNA binding protein for Sso7d in such a complex, it would have been obvious to look to Guo's disclosure of Cren7 as being such a similar dsDNA-binding protein, which may in fact be even more efficient at functioning to enhance processivity than Sso7d, when seeking alternative dsDNA binding proteins to complex with DNA polymerase. Therefore, we are not persuaded by Appellants' arguments that there would not have been a motivation to combine Guo and Wang as the Examiner has done in rejecting the claims.

Appellants argue the Examiner's rejection considers "Guo solely for its description of the biochemical and structural characteristics of Cren7," the protein of the claims. Appeal Br. 5. This position is not persuasive. It overlooks the Examiner's point that Guo compares Cren7 *Sulfolobus solfataricus* protein with the Sul7d protein (which is like Sso7d; specifically, Sac7d, as specified in Guo per its *Sulfolobus acidocaldarius* origins). It further overlooks that Guo indicates that Cren7 and Sac7d are very structurally and functionally similar, e.g., in residue number, hydrophobic regions, positively charged regions, etc. Because of these similarities, as explained by Guo, it would have been obvious to substitute Cren7 for Sso7d/Sac7d from *Sulfolobus solfataricus* in the engineered complexes with DNA polymerases as taught by Wang.

Appellants argue there was "great uncertainty about the role of any individual suspected chromatin protein" and there were "clear structural differences between [the claimed] Cren7 and the protein [Sul7d]," such as presence of a flexible loop, hydrophobic region, hinge region, as discussed in Guo at pages 1134–35, resulting in different DNA binding footprints and DNA interactions. Appeal Br. 8–9 (citing the Danson Declaration[4] and the Morant Declaration[5]).

While we agree that Guo indicates there are differences between Cren7 and Sul7d, as contended by Appellants, the main point of Guo is how similar Cren7 and Sul7d and/or Sac7d are to one another when

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[4] Declaration of M.J. Danson, Ph.D., Under 37 C.F.R. § 1.132, dated January 15, 2015 ("Danson Declaration").
[5] Declaration of Nicholas Morant, Ph.D., Under 37 C.F.R. § 1.132, dated October 29, 2015 ("Morant Declaration").

characterizing Cren7. Furthermore, Guo identifies that Cren7 has the very qualities, i.e., thermostability and non-specific dsDNA binding, indicated by Wang as desirable for its disclosed DNA polymerase complex. Moreover, contrary to Appellants' contention, Guo cannot be said to indicate that the differences between Cren7 and Sul7d outweigh their similarities; there is simply no context for such an assertion. We note that the Danson Declaration urges that there are significant differences between Cren7 and Sso7d; however, the Declaration essentially restates the differences identified by Guo itself. Danson Declaration ¶ 6 (citing Zhang; however Zhang indicates that "Cren7 resembles Sul7d in both biochemical properties and structure" in spite of the differences and maintains, as in Guo, that "Cren7 is about twice as efficient as Sac7d/Sso7d in containing DNA supercoils, as estimated biochemically (. . . Guo *et al*. 2008)")[6].

Appellants argue "Wang provides no suggestion[s] to substitute a Cren7 domain for the Sso7d domain in . . . [its] DNA polymerase fusion protein." Appeal Br. 9–10. Appellants note that Wang mentions the possibility of using "other types of dsDNA binding proteins in place of Sso7d," but contend Cren7 would not be that substitute. *Id.* at 10. Appellants argue the number of possible substitutes is vast and choosing one would require "extensive experimentation." *Id.* at 10–11.

This is not persuasive. Wang may not have an explicit suggestion for substituting Cren7 for its Sso7d protein, but Guo, as discussed above,

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[6] Zhenfeng Zhang et al., *Structural Insights Into the Interaction of the Crenarchaeal Chromatin Protein Cren7 with DNA*, 76 MOLECULAR MICROBIOLOGY, 749–59, 756 (2010).

identifies that the two proteins are very similar, including in ways important for forming Wang's DNA polymerase complex. Thus, rather than sorting through hundreds of possible dsDNA binding proteins, as argued by Appellants, a skilled artisan having Wang and Guo in hand would reasonably focus on Cren7, as it is so identified by the references as usefully similar to Sso7d.

Appellants argue the Examiner has failed to articulate a basis for finding motivation to combine Guo and Wang. Appeal Br. 12, 14. Appellants contend the Examiner's rationale that "'[t]he motivation for the substitution of the Cren7 protein domain for the Sso7 protein domain is that both protein domains are similar small, basic, dsDNA binding proteins of approximately 60 amino acids'" is insufficient. *Id.* (citation omitted).

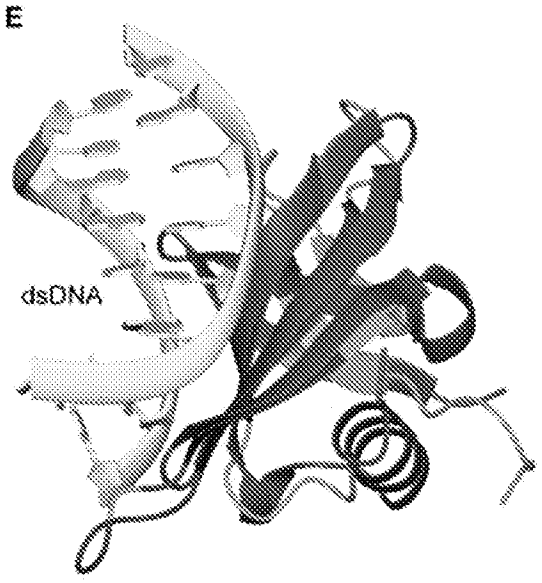
We have addressed similar contentions by Appellants above. Guo explains why such a substitution would be advantageous. First, Guo indicates that Cren7 is thermostable and has non-specific dsDNA binding, which are the requirements for a complexing protein as indicated by Wang (at 1200), and, further, Guo indicates that compared to Sul7d (i.e., Sac7d/Sso7d), "Cren7 is about twice as efficient . . . in constraining DNA supercoils," and that "binding by Cren7 significantly increas[es] the stability of dsDNA against thermal denaturation." Guo 1132–33. Wang emphasizes that such "[b]inding of . . . [the protein] to dsDNA is important for . . . processivity" (emphasis omitted), and that this increase in processivity "allows the polymerase to incorporate more nucleotides per binding event . . . [to make it] more efficient *in vitro* replication." *See* Wang 1201–03. Thus, Cren7's enhanced binding efficiency over Sso7d would be an

advantage, making its substitution for Wang's protein reasonable and obvious. As also discussed above, the smallness of the Cren7 molecule, pointed to by the Examiner, is also an advantage so as not to perturb the fusion partner.

Appellants argue there are significant structural differences between Cren7 and Sso7d that would have caused a skilled artisan not to substitute Cren7 for Sso7d in Wang's complex. Appeal Br. 13 (citing Danson Declaration).

This is not persuasive. This issue has been addressed above, but regarding the structural comparison between Cren7 and SSo7d/Sul7d/Sac7d, the Examiner takes a contrary position. The Examiner points out that Guo focuses on the biochemical and structural similarities between the two proteins, e.g., they are SH3-like folding proteins, both bind only weakly to ssDNA in low salt, both bind preferentially to dsDNA, the two proteins share structural similarity when compared upon alignment by Dali (RMSD of 2.6Å; Z-score of 2.8; of the 60 residues in Cren7 and 66 residues in Sac7d, 44 are aligned), the β-barrel parts of the proteins align, the two proteins share similar solvent exposed hydrophobic regions and positively charged regions on the β-sheet 2 (these form the DNA-binding surfaces), many residues on the DNA-bindings surfaces of the proteins are conserved or similar (including positively charged residues, hydrophobic residues, tryptophan residue. Answer 10. The Examiner notes that Guo identifies these similarities as well as the differences that are the focus of Appellants' arguments, but determined that the similarities would outweigh the

differences. *Id.* at 11, 13. The Examiner calls these "extraordinary similarities." *Id.* (citing Guo Figure 5E in color, reproduced below).



As explained in Guo:

> **Figure 5** [shows the] DNA-binding surface of Cren7. . . . (**E**) Cren7 is aligned with Sac7d in the Sac7d–dsDNA complex [with bound dsDNA shown in yellow]. Cren7, green and blue, as in Figure 5C; Sac7d, red.

Guo 1135. Guo's Figure 5E, above, shows that, despite the differences in amino acid sequence and other differences in structure, Cren7 and Sac7d (and, therefore Sso7d) very similarly bind to dsDNA, which is Wang's objective in including Sso7d in a DNA polymerase complex. Thus, it would be reasonable to expect Cren7 would successfully bind DNA, like Sso7d, when substituted for Wang's Sso7d protein in a DNA polymerase complex. Furthermore, the Examiner points out that Wang actively encourages the use of other dsDNA binding proteins, similar to Sso7d, for the same purpose of enhancing processivity. Moreover, the Examiner explains that Guo's

identification of the similarities between Cren7 and Sac7d, which itself is very similar to Wang's Sso7d, would make Cren7 a reasonable choice for such substitution. Answer 11–12.

Appellants argue (or more accurately, imply) that, based on the data presented in the Morant Declaration, the invention provides an increased salt tolerance, which was unexpected compared to Sso7d-Taz chimera. Appeal Br. 13.

We are not persuaded by this argument or evidence. The Examiner responds to Appellants' argument, determining that the results discussed by the Morant Declaration are not commensurate with the scope of the claimed invention, which is directed to SEQ ID NO:1; the experimental data does not relate to proteins as broadly claimed. Answer 14–15. The data set forth in the Morant Declaration was a comparison of *Sso*7d-*Taq*pol, which corresponds with the Wang complex, with the following three Cren7-DNA polymerase complexes: *Hbu*Cren7-*Taq*pol; *Ape*Cren7-T*aq*pol; and *Ign*Cren7-*Taq*pol. The Morant Declaration showed improved salt tolerance in the latter three complexes compared to the first.

The Examiner determined:

> It is noted that specific evidence to which Appellants refer is that of a comparison of the salt concentration dependent activity of ApeCren7-Taqpol (SEO ID NO: 7), HbuCren7-Taqpol (SEQ ID NO:5/6) and IgnCren7-Taqpol (SEQ ID NO: 9), Sso7d-Taqpol and Taqpol. ***It is noted that Appellants present evidence of KCL concentration dependence of polymerase activity of 3 species of Cren7-Taqpols having 74.6%/73% (Hbu, SEQ ID NO: 5/6), 65.6% (Ape, SEQ ID NO: 7) and 53.3% (Ign, SEQ ID NO: 9) sequence identity to SEQ ID NO: 1.*** While it is interesting that each of these 3 species shows a different level of KCL concentration dependence of polymerase activity, it is noted that

> Appellants have not disclosed the KCL concentration dependence of polymerase activity of the Cren7-Taqpol of Sso (SEQ ID NO:I) which claim 1 is directed to. Thus the "unexpected results" that Appellants evidence are not commensurate in scope with the claims, drawn to those chimeric proteins comprising a Cren7 enhancer domain having at least 35% sequence identity to SEQ ID NO:1, which the evidence is offered to support.

Answer 15. The Examiner is correct and, moreover, besides not disclosing results at the bookend of identity where the domain is exactly the same as SEQ ID NO:1, the data, like the Specification as discussed above in relation to the § 112 rejection, does not reflect results representative of the lower bookend of sequence identity, i.e., a domain 35% similar to SEQ ID NO:1. The closest the evidence comes is a domain with 53.3% identity, but without identifying the relevant structural characteristics that would be commonly required for functionality.

"Commensurate in scope" means that the evidence provides a reasonable basis for concluding that the untested embodiments encompassed by the claims would behave in the same manner as the tested embodiment(s). *See Lindner*, 457 F.2d at 508 ("Here, only one mixture of ingredients was tested. . . . The claims, however, are much broader in scope, . . . and we have to agree with the Patent Office that there is no 'adequate basis for reasonably concluding that the great number and variety of compositions included by the claims would behave in the same manner as the [single] tested composition.'") (citation omitted) (bracketed material in original). We agree with the Examiner that the proffered evidence is not commensurate in scope with the claimed invention. Therefore, it is not persuasive to overcome the Examiner's prima facie case of obviousness.

For the reasons set forth above, we are unpersuaded that the Examiner erred in presenting a prima facie case for obviousness or that sufficient secondary indicia of non-obviousness has been provided to establish patentability. The balance of evidence on appeal favors the Examiner's position.

SUMMARY

The rejection for lack of written description rejection under 35 U.S.C. § 112 is affirmed.

The obviousness rejection under 35 U.S.C. § 103 is affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED