

The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper No. 130

Filed by: Trial Section Motions Panel
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

KOZO SHIOKAWA, SHINICHI TSUBOI, KOICHI MORIYA,
YUMI HATTORI, IKURO HONDA and KATSUHIKO SHIBUYA

Junior Party,
(Patent 5,719,146),

v.

PETER MAIENFISCH and LAURENZ GSELL

Senior Party
(Application 09/136,664).

Patent Interference No. 104,525

Before: McKELVEY, Senior Administrative Patent Judge, and TORCZON and TIERNEY, Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

MEMORANDUM OPINION and ORDER
(Decision on Preliminary Motions)

This interference is before a motions panel for a decision on preliminary motions. Oral argument took place on March 19, 2001. Present at oral argument for Junior Party Shiokawa was Charles L. Gholz, Esq. Senior Party Maienfisch was represented by James Galbraith, Esq.

Summary of the Opinion

Notwithstanding the numerous issues and subissues raised by the parties, this interference in simplest form involves only two questions. First, is Shiokawa entitled to the benefit for the purposes of priority of the filing dates of its earlier Japanese (JP) and U.S. applications. Secondly, does Shiokawa's published Japanese application JP 1-54943 (JP '943) or Shiokawa U.S. Patent 5,032,589 ('589 patent) anticipate or render obvious Maienfisch's claimed 1,3,5-oxadiazines.

As to the first question, Shiokawa's earlier applications do not describe the subject matter of the count, thus, for purposes of priority, Shiokawa is not entitled to the benefit of the filing dates of the earlier JP and U.S. applications. As stipulated by the parties, since Shiokawa is not entitled to the priority benefit of the filing date of its earlier applications, Maienfisch's published European patent application EP 580,553 anticipates, and renders unpatentable, the claims of the '146 patent under 35 U.S.C. § 102(b). (Stipulation, Paper No. 28, p. 1). Additionally, as noted during oral argument, there would be no priority testimony in this interference proceeding, i.e., a decision on Shiokawa's priority benefit determines the outcome on priority of invention. Accordingly, as Shiokawa is not entitled to the benefit of its earlier filing dates, Maienfisch prevails on priority of invention.

As to the second question, to the extent that Shiokawa's JP '943 and U.S. '589 disclosures may suggest that certain classes of heterocyclic compounds, such as Maienfisch's claimed oxadiazines, would be effective as insecticides, Maienfisch, has presented credible and convincing evidence of unexpected results for its claimed 1,3,5-oxadiazines. Accordingly, we conclude that Shiokawa has

failed to demonstrate that Maienfisch's claimed 1,3,5-oxadiazines would have been obvious to one skilled in the art given the teachings of the Shiokawa JP '943 reference or the Shiokawa '589 patent.

I. Findings of Fact

The record supports, by a preponderance of the evidence, the following findings.

A. The Interference

1. The interference involves Shiokawa et al., U.S. Patent No. 5,719,146 (Shiokawa '146) versus Maienfisch et al., U.S. Application 09/136,664 (Maienfisch '664). (Paper No. 1 "Notice Declaring Interference"). Shiokawa is the junior party and Maienfisch is the senior party.

B. The Junior Party

2. Nihon Bayer Agrochem K.K. is the real party in interest in Shiokawa '146 and Bayer AG is the exclusive licensee. (Shiokawa Designation of Real Party in Interest, Paper No. 5, p. 1). Shiokawa '146 issued from U.S. application 08/597,780 filed on February 7, 1996. (Shiokawa '146, SX 2003, front page).

C. The Senior Party

3. Novartis Corporation is the real party in interest in Maienfisch '664 which was filed on August 19, 1998. (Maienfisch Designation of Real Party in Interest, Paper No. 10, p. 2). For purposes of priority, Maienfisch '664 has been accorded the benefit of the filing dates of:

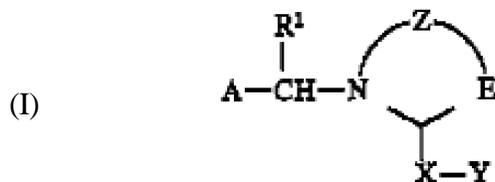
- a. U.S. Application No. 08/464,931, filed June 5, 1995, now U.S. Patent No. 5,852,012 issued December 22, 1998.
- b. U.S. Application No. 08/270,612, filed July 5, 1994, now abandoned.
- c. U.S. Application No. 08/091,801, filed July 14, 1993, now abandoned.
- d. Swiss Patent Application 2315-92-1, filed July 22, 1992.

(Paper No. 1, p. 46).

D. Disclosures of the Application and Patent Involved in the Interference

1. Shiokawa's '146 Patent

4. Shiokawa '146 is said to describe insecticidal compounds, a process for their preparation and the use of the compounds as insecticides. (SX 2003, col. 1, lines 8-10). In particular, Shiokawa '146 describes a genus of insecticidal compounds have the following formula (I):

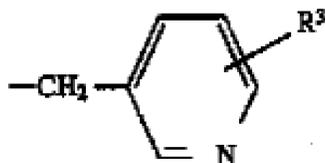


wherein:

A represents a five-membered or six-membered heteroaryl group comprising one to three hetero atoms selected from the group consisting of S, O and N and the heteroaryl group being unsubstituted or substituted by a halogen atom or C₁₋₄ alkyl group;

Z represents a three-membered straight chain each member being selected from the group consisting of CH₂, O, S and N-R² *with at least one of said three members being O, S or N--R²*;

E represents *CH₂, O, S or N--R²*, wherein R² represents a hydrogen atom, a C₁₋₄ alkyl group, a C₁₋₄ alkoxy group or the group:



R³ represents a or the group hydrogen atom or halogen atom;
 X represents CH or N, Y represents a nitro group or cyano group; and,
 R¹ represents a hydrogen atom or methyl group.

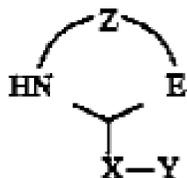
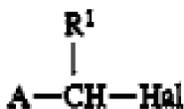
(SX 2003, col. 1, lines 18-45, emphasis added). The preferred compounds are those in which:

A is limited to 2-chloropyridin-5-yl or 2-chlorothiazol-5-yl;
 Z is limited to a three-membered straight chain, each member being selected from the group consisting of CH₂, O, S and N-R², *with at least one of said three members being O, S or N-R²*;
 E is limited to **CH₂, O, S or N-R²**;
 R₂ is limited to a C₁₋₃ alkyl group, a C₁₋₃ alkoxy group or 2-chloropyridin-5yl methyl;
 X is limited to N; and,
 Y is limited to a nitro group or cyano group.

(SX 2003, col. 2, lines 8-15, emphasis added).

5. Shiokawa '146 does not state a preference for a particular compound or subset of compounds falling within the scope of the "preferred compounds" of the invention. Similarly, beyond the explicitly defined "preferred compounds," Shiokawa '146 does not direct one skilled in the art to select one particular exemplified compound over another.

6. According to Shiokawa '146, the heterocyclic compounds of the invention can be obtained by reacting compounds of formula II (depicted below) with compounds of formula III (depicted below).

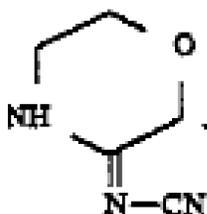


Formula (II)

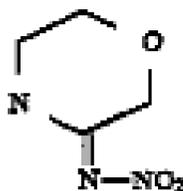
Formula (III)

wherein A, R¹, Z, E, X and Y have the same meanings as recited above and Hal represents a halogen atom. (SX 2003, col. 1, lines 46-63). Shiokawa '146 states that "some of the starting materials of the formula (III) are novel, and can be obtained as outlined below." (SX 2003, col. 2, lines 54-55). Shiokawa then proceeds to identify three specific compounds which can be used as the starting materials of formula (III), specifically:

(1) 3-cyano-iminomorpholine of the formula:

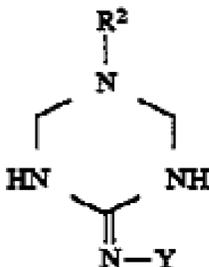


(2) 3-nitroiminomorpholine having the formula:



(3) 1,3,5-triazines¹ having the general formula (III') depicted below:

Formula (III')



(SX 2003, col. 2, line 55 to col. 3, line 53). Shiokawa '146 provides three examples, Examples 5-7, describing the preparation of 1,3,5-triazine intermediate compounds that fall within the scope of general formula (III'). (SX 2003, col. 17, line 26 to col. 18, line 43).

7. Shiokawa '146 provides four examples of the preparation of compounds of the invention. In particular, Example 1 describes the preparation of a 3-cyanoiminomorpholine heterocyclic intermediate compound and the subsequent formation of 4-(2-chloro-5-pyridylmethyl)-3-cyanoiminomorpholine. Example 2 describes the preparation of 5-methyl-2-nitroimino-hexahydro-1,3,5-triazine. Example 3 describes the preparation of 5-methyl-2-cyanoimino-hexahydro-1,3,5-triazine. Example 4 describes the preparation of 1-(2-chloro-5-pyridylmethyl)-5-methoxy-2-nitroimino-hexahydro-1,3,5-triazine.

¹The term "1,3,5-triazine" refers to a six-membered ring bearing three nitrogen heteroatoms, the ring being in its fully unsaturated form, i.e., the ring contains three double bonds. (Nomenclature of Organic Chemistry, IUPAC, SX 2097, p. 54). As the attorneys and experts for both Shiokawa and Maienfisch have adopted the term 1,3,5-triazines as shorthand for the fully saturated hexahydro-1,3,5-triazines, we will follow the parties lead and likewise adopt the term "1,3,5-triazines" as shorthand for the compound hexahydro-1,3,5-triazine. (Shiokawa Motion 13, Paper No. 102, p. 7, fn. 4 and SX 2096, p.4, fn. 3).

Thus, example 1 describes a 3-cyanoiminomorpholine compound whereas examples 2-4 describe 1,3,5-triazine compounds.

8. The '146 patent does not explicitly state a preference for the exemplified compounds.

Moreover, the '146 patent does not identify any of the exemplified compounds as exhibiting better or worse insecticidal properties than the others. The '146 patent merely states that: "The preparation and use of the active compounds according to the invention can be seen from the following examples." (SX 2003, col. 6, lines 65-67).

9. The 4-(2-chloro-5-pyridylmethyl)-3-cyanoiminomorpholine formed in example 1 of the '146 patent is encompassed by Shiokawa's described "preferred" subgenus of insecticidal heterocyclic compounds. Specifically, in the compound 4-(2-chloro-5-pyridylmethyl)-3-cyanoiminomorpholine: A is 2-chloro-5-pyridin-5yl methyl; R¹ is H; Z is -CH₂-CH₂-O-; E is CH₂; X is N; and, Y is CN (a cyano group). Accordingly, each of the A, R¹, Z; E, X, Y variables for the compound of example 1 is encompassed within the definition given for the "preferred" compounds. (See SX 2003, col. 2, lines 4-15).

10. The compounds of examples 2, 3 and 4 do not fall within the "preferred" subgenus of insecticidal heterocyclic compounds as described by the '146 patent. Specifically, the '146 patent states that preferred compounds according to the invention are those in which R² represents a C₁₋₃ alkyl group, a C₁₋₃ alkoxy group or 2-chloro-5-pyridin-5yl methyl. Each of the "desired" heterocyclic

compounds formed in examples 2, 3 and 4 possess an E group that is N-R² where R² is H. (See SX 2003, examples 2-4 and structures depicted therein).

11. When the intermediate compounds of examples 5, 6 and 7 were employed in examples 2, 3 and 4, the stated result was not a preferred heterocyclic compound of the '146 patent. Examples 5, 6 and 7 describe the preparation of an intermediate compound that possesses an E moiety where E is N-R² and where R² is H. (SX 2003, examples 5-7 and structures depicted therein). The compounds of examples 5, 6, and 7 were used in examples 2, 3 and 4 as follows:

(1) An intermediate compound of example 5 (5-methoxy-2-nitroimino-hexahydro-1,3,5-triazine) was reacted with 2-chloro-5-chloromethyl-pyridine in example 4. The resulting "desired" compound was not a preferred compound of the invention.

(2) An intermediate compound of example 6 (5-methyl-2-nitroimino-hexahydro-1,3,5-triazine) was reacted with 2-chloro-5-chloromethyl-pyridine in example 2. The resulting "desired" compound was not a preferred compound of the invention.

(3) An intermediate compound of example 7 (5-methyl-2-cyanoimino-hexahydro-1,3,5-triazine) was reacted with 5-chloro-2-chloromethylpyridine in example 3. The resulting "desired" compound was not a preferred compound of the invention.

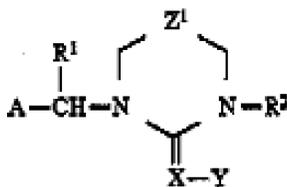
12. According to Shiokawa '146, compounds that can be prepared in analogous reactions to those of examples 1-4 are depicted in Table 1. (SX 2003, col. 8, lines 58-61). Table 1 depicts the structures of forty compounds, four of which were those obtained in examples 1-4. Not one of the

thirty-six compounds which could be prepared by reactions analogous to examples 1-4 was a 1,3,5-oxadiazine.

13. In Shiokawa examples 8 and 9, the compounds of Table 1, numbered 2, 3, 11, 12, 14, 15, 16, 17 and 40 were allegedly tested for their insecticidal properties. (SX 2003, col. 18, line 45 to col. 19, line 28). The tested compounds were said to exhibit a 100% insect mortality rate when tested at concentrations of 200 ppm and 500 ppm. (SX 2003, col. 19, lines 3-5 and 26-28).

14. Shiokawa claim 1 reads as follows:

A heterocyclic compound of the formula:



wherein

A represents 2-chloropyridin-5-yl or 2-chlorothiazol-5-yl;

Z¹ represents O;

R² represents a hydrogen atom, a C₁₋₄-alkyl group or 2-chloropyridin-5-ylmethyl;

X represents CH or N;

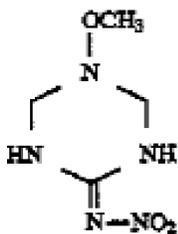
Y represents NO₂ or CN; and

R¹ represents a hydrogen atom or a methyl group.

(SX 2003, claim 1). The claimed compound is a 1,3,5-oxadiazine due to the presence of the oxygen atom (O) in “1” position and the nitrogen atoms (N) in the “3” and “5” positions of the ring structure on

the right hand side of the formula. In contrast a 1,3,5-“triazine” has nitrogen atoms in the 1, 3 and 5 positions of the ring.

15. There is a dispute as to the reaction mechanisms and products formed in Shiokawa example 5. Specifically, Shiokawa argues that the process recited in example 5 would lead to the inherent formation of a 1,3,5-oxadiazine intermediate compound, i.e. a compound of Shiokawa formula (III) where Z is CH₂-O-CH₂ and E is N-R₂. Yet, Shiokawa example 5 is directed to the “preparation of an intermediate compound” having the formula:



(SX 2003, example 5, col. 17, lines 26-35, i.e., a compound of Shiokawa formula (III) where Z is CH₂-N(OCH₃)-CH₂ and E is NH). Example 5 specifically states that:

A mixture consisting of *nitroguanidine* (10 g), *methoxyamine hydrochloride* (9.6 g), 75% *paraformaldehyde* (11.5 g), toluene (80 ml) and a catalytic amount of concentrated hydrochloric acid was subjected to heating under reflux for three hours, **while the water was removed therefrom.**^[2] Under reduced pressure, the solvent contained in the mixture was distilled off to obtain white crystals of the hydrochloride of 5-methoxy-2-nitroimino-hexahydro-1,3,5-triazine (16.2 g) having a melting point from 160° to 170 °C.

(SX 2003, example 5, lines 36-46, emphasis added to highlight reactants and removal of water).

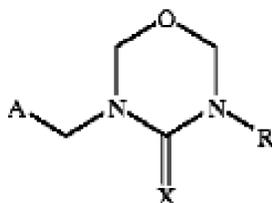
Nowhere does Shiokawa '146 mention the formation of a 1,3,5-oxadiazine intermediate compound, let

²Depicted on p. 247 of Petersen “Synthesis of Cyclic Ureas by α -Ureidoalkylation” (SX 2051) is a reaction of a 1,3,5-oxadiazine compound and a hydrochloride salt of a methyl amine. This reaction is depicted as forming hexahydro-1,3,5-triazine, water and HCl. Shiokawa, having relied upon the Petersen reference, fails to sufficiently explain why such a reaction would not occur in example 5 of the '146 patent. Moreover, if such a reaction does occur in example 5, Shiokawa has failed to sufficiently explain why the removal of the water from the process of example 5 of the '146 patent would not drive the reaction toward the 1,3,5-triazine and away from the 1,3,5-oxadiazine.

alone mention its formation in example 5. It is possible, of course, that a detectable quantity of a 1,3,5-oxadiazine intermediate compound might be formed in the process of Shiokawa's example 5. (SX 2056, pages 2-4). Still, the formation of a 1,3,5-oxadiazine was not a stated result of the example 5 reaction process, and there is no indication that the Shiokawa inventors were aware that such a compound was potentially formed by the process of example 5. Indeed, example 5 does not clearly convey to one of ordinary skill in the art that the inventors had formed a 1,3,5-oxadiazine compound or that the inventors possessed such a compound.

2. Maienfisch's '664 Application

16. Maienfisch '664 describes compounds having the following formula:



wherein:

A is an unsubstituted or mono- to tetrasubstituted, aromatic or non-aromatic, monocyclic or bicyclic heterocyclic radical, where one to two of the substituents of A can be selected from the group consisting of halo-C₁-C₃ alkyl, cyclopropyl, halocyclopropyl, C₂-C₃ alkenyl, C₂-C₃ alkynyl, halo-C₂-C₃ alkenyl, halo-C₂-C₃ alkynyl, halo-C₁-C₃ alkoxy, C₁-C₃ alkylthio, halo-C₁-C₃ alkylthio, allyloxy, propargyloxy, allylthio, propargylthio, haloallyloxy, haloallylthio, cyano and nitro, and one to four of the substituents of A can be selected from the group consisting of C₁-C₃ alkyl, C₁-C₃ alkoxy and halogen;

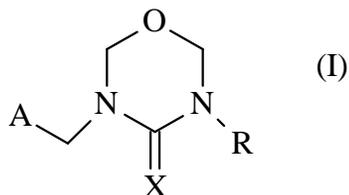
R is hydrogen, C₁-C₆ alkyl, phenyl-C₁-C₄ alkyl, C₃-C₆ cycloalkyl, C₂-C₆ alkenyl or C₂-C₆ alkynyl; and

X is N-NO₂ or N-CN.

(Maienfisch '644 application, SX 2016, p. 1). The compounds may be in free form or in salt form, and, if appropriate, to tautomers thereof, in free form or in salt form. (SX 2016, p. 1). Maienfisch '644 also describes processes for the preparation and to the use of the above compounds and tautomers as pesticides. (SX 2016, p. 1).

17. Maienfisch claim 24 reads as follows:

A compound of the formula:



an agrochemically utilizable salt of said compound of the formula I, a tautomer of said compound of the formula I, or an agrochemically utilizable salt of said tautomer, wherein in formula I

A is 2-chloropyrid-5-yl or 2-chlorothiazol-5-yl,

R is hydrogen or C₁-C₄ alkyl; and

X is N-NO₂ or N-CN.

(SX 2017, claim 24). As with Shiokawa claim 1, the compound of Maienfisch claim 24 is a 1,3,5-oxadiazine as the oxygen atom (O) is in “1” position and the nitrogen atoms (N) are in the “3” and “5” positions of the ring structure on the right hand side of the formula.

E. The Count

18. The interference was declared on April 7, 2000, (Paper No. 1), with Count 1 which reads as follows:

A compound according to claim 1 of Shiokawa or claim 24 of Maienfisch,

or

a composition according to claim 2 of Shiokawa or claim 26 of Maienfisch,

or

a method according to claim 3 of Shiokawa or claim 27 of Maienfisch.

(Paper No. 1, p. 47, Paper No. 50 and Paper No. 62).

19. As set forth in the Order Granting Shiokawa Preliminary Motion 2, Paper No. 50, Maienfisch claims 26 and 27 were held unpatentable as being indefinite under the second paragraph of 35 U.S.C. §112. Per Paper No. 50, Maienfisch timely filed an amendment canceling claims 26 and 27 and adding new claims 28 and 29 which depend from independent claim 24. (Maienfisch Filing of Amendment, Paper No. 62). Thus, as set forth in Paper No. 50, the Board sua sponte replaces Count 1 with Count 2 to reflect the cancellation of Maienfisch claims 26 and 27 and the addition of new claims 28 and 29. Count 2 reads as follows:

A compound according to claim 1 of Shiokawa or claim 24 of Maienfisch,

or

a composition according to claim 2 of Shiokawa or claim 28 of Maienfisch,

or

a method according to claim 3 of Shiokawa or claim 29 of Maienfisch.

20. The claims of the parties are as follows:

(i) The claims of the parties are:

Shiokawa '146 :	1-3
Maienfisch '664:	24-25 and 28-29

(ii) The claims of the parties which corresponded to Count 2 are:

Shiokawa '146 :	1-3
Maienfisch '664:	24-25 and 28-29

(iii) The claims of the parties which did not correspond to Count 2 are:

Shiokawa '146 :	None
Maienfisch '664:	None

(Paper No. 1, p. 47, Paper No. 50, and Paper No. 63).

21. The accorded priority benefit is the same for Count 2 as it was for Count 1. (See Paper No. 1, p. 46).

II. Opinion

A. Overview of Preliminary Motions

There are five pending preliminary motions. In particular, Shiokawa has four pending preliminary motions: (1) Corrected Preliminary Motion 1³ (seeking priority benefit of earlier filed applications); (2) Preliminary Motion 4 (unpatentability of Maienfisch's claims under 35 U.S.C. § 102 and § 103); (3) Preliminary Motion 13 (suppress Maienfisch exhibit 1001); and (4) Preliminary Motion 14 (suppress Maienfisch exhibits 1005, 1006 and paragraphs 48-49 of Maienfisch exhibit 1001). In contrast, Maienfisch has only one pending preliminary motion, Preliminary Motion 1 (unpatentability of Shiokawa's claims under 35 U.S.C. § 112, first paragraph for lack of written description). With the exception of Shiokawa Preliminary Motion 3, all other preliminary motions have either been withdrawn or have been decided.⁴

³Shiokawa filed Corrected Preliminary Motion 1 to correct an error that occurred in paragraph 11 of the statement of facts of its Preliminary Motion 1. Specifically, Shiokawa replaced the language "twenty-one compounds described in the '146 patent have a Z group containing one oxygen atom bonded to CH₂ groups on either side" with "twenty-one compounds described in the '146 patent have a Z group consisting of one oxygen atom and two CH₂ groups." (See Papers 34, 72, 73 and 74).

⁴ Shiokawa Preliminary Motion 2 (Paper No. 35; unpatentability of Maienfisch's claims under 35 U.S.C. § 112, second paragraph; **Granted**, Paper No. 50).

Shiokawa Preliminary Motion 5 and Supplement to Preliminary Motion 5 (Paper Numbers 38 and 64; substitute or add counts; **Withdrawn**, Paper No. 124)

Shiokawa Preliminary Motion 6 (Paper No. 39; benefit for proposed count S-1; **Withdrawn**, Paper No. 124)

Shiokawa Preliminary Motions 7, 8 and 9 (Paper Numbers 41, 42, 43; add additional applications; **Denied**, Paper No. 49)

Shiokawa Preliminary Motions 11 and 12 (Paper Numbers 53 and 56; motions for discovery; **Denied**, Paper No. 63).

Maienfisch Preliminary Motion 2 (Paper No. 75; discovery; **Granted**, Paper No. 78).

Technically, Shiokawa Preliminary Motion 3 (Paper No. 36) is still undecided. Shiokawa Preliminary Motion 3 alleges that Maienfisch's claims are unpatentable due to double patenting over Maienfisch's U.S. Patent No. 6,022,871 (SX 2011). Maienfisch, however, has filed a terminal disclaimer (Paper No. 85, MX 1038) that obviates Shiokawa's double patenting concerns. Accordingly, Shiokawa Preliminary Motion 3 is *denied*.

B. Shiokawa Corrected Preliminary Motion 1 for Priority Benefit

Shiokawa moves for priority benefit of the filing dates of its earlier JP and U.S. patent applications. (Shiokawa Corrected Preliminary Motion 1, Paper No. 74, p. 1). Specifically, Shiokawa seeks benefit for the purposes of priority of the following applications:

- (1) Japanese patent application JP 1-54943, filed March 09, 1989.
- (2) U.S. Application Ser. No. 07/487,004, filed March 01, 1990.
- (3) U.S. Application Ser. No. 07/658,933, filed February 21, 1991.
- (4) U.S. Application Ser. No. 07/870,178, filed April 16, 1992.

(Paper No. 74, p. 1). The '146 patent is said to be a divisional of the 07/870,178 application which is said to be a continuation of the 07/658,933 application which itself is said to be a continuation of the 07/487,004 application. (Paper No. 74, ¶1, 2, 3). The 07/487,004 application and its children are said to claim benefit under 35 U.S.C. §119 of the filing date of the JP 1-54943 application. (Paper No. 74, ¶6). The disclosures of Shiokawa '146, its three U.S. parent applications and its JP priority application are essentially identical. (Paper No. 74, ¶7, Maienfisch Opposition 1, Paper No. 83, p. 2).

1. Case Law Analysis for According Priority Benefit

For Shiokawa to have benefit of the earlier filing dates, Shiokawa must demonstrate that its earlier applications constituted a constructive reduction to practice of the subject matter of the count. *Credle v. Bond*, 25 F.3d 1566, 1570, 30 USPQ 1911, 1914 (Fed. Cir. 1994). For an earlier-filed application to serve as constructive reduction to practice, “the applicant must describe the subject matter of the count in terms that establish that he was in possession of the later-claimed invention, including all of the elements and limitations presented in the count, at

the time of the earlier filing.” *Hyatt v. Boone*, 146 F.3d 1348, 1353-54, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998). Moreover, “it is insufficient as written description, for purposes of establishing priority of invention, to provide a specification that does not unambiguously describe all limitations of the count.” *Id.*

While the specifics of the cases concerning adequate written description vary, the cases agree that the inquiry is *factual* and must be assessed on a *case-by-case* basis. Moreover, because of the fact-sensitive nature of the written description inquiry, the Federal Circuit has advised against misapplication of precedent in this area. See, *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 1000, 54 USPQ2d 1227, 1235 (Fed. Cir. 2000); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); and, *In re Driscoll*, 562 F.2d 1245, 1250, 195 USPQ 434, 438 (CCPA 1977).

The purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by the inventor. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. The inventor can demonstrate possession by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. The inventor, however, needs to show that the inventor was "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. Thus, entitlement to a filing date does not extend to subject matter which is not disclosed, but would have been obvious over what is expressly disclosed. It extends only to that which is disclosed. A description which renders obvious the invention for which an earlier filing

date is sought is not sufficient. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571-72, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The disclosure as originally filed does not have to provide *ipsis verbis* support for the claimed subject matter at issue. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed. Cir. 1996). Rather, if the written description does not use precisely the same terms used in a claim, the question then is whether the specification directs or guides one skilled in the art to the subject matter claimed such that the specification reasonably conveys to those skilled in the art that the inventor invented what is claimed. *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d at 1570, 39 USPQ2d at 1904 (Fed. Cir. 1996); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116; *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

As a backdrop to our factual inquiry into Shiokawa's written description, we provide an overview of several of the cases that have been frequently cited in this interference - *Fujikawa v. Wattanasin* and *In re Driscoll* as well as the decision in *In re Smith*. These cases involved a later claimed subgenus that sought support in originally filed disclosures that described a genus or both a genus and one or more species.

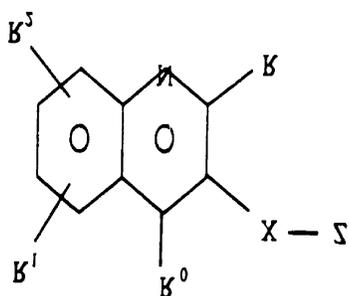
i. *Fujikawa v. Wattanasin*⁵

Fujikawa involved an appeal from two interference decisions of the Board of Patent Appeals and Interferences ("Board"), *inter alia*, denying *Fujikawa*'s preliminary motion to add an additional

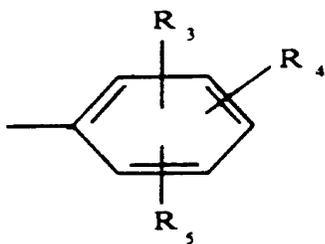
⁵ 93 F.3d 1559, 39 USPQ2d 1895 (Fed. Cir. 1996).

sub-genus count to the interferences. The subject matter on appeal was directed to a compound and method for inhibiting cholesterol biosynthesis in humans and other animals. A compound count recited a genus of novel mevalonolactones whereas a method count recited a method of inhibiting the biosynthesis of cholesterol by administering to a "patient in need of said treatment" an appropriate dosage of a compound falling within the scope of the compound count. *Fujikawa*, 93 F.3d at 1561, 39 USPQ2d at 1896.

Fujikawa's preliminary motion to add an additional sub-genus count to the interference was denied by the Board because it determined that junior party Wattanasin's disclosure did not sufficiently describe Fujikawa's proposed count. *Id.* at 1570, 39 USPQ2d at 1904. Specifically, Wattanasin's application disclosed compounds of the following structure:



wherein each of R and R₀ is, independently, C₁₋₆ alkyl (primary, secondary, or tertiary), C₃₋₇ *cycloalkyl*, or the following ring,



and each of R₁, R₂, R₃, R₄, and R₅ is, independently, **hydrogen**, C₁₋₄ alkyl, C₁₋₄ alkoxy, trifluoromethyl, **fluoro**, chloro, phenoxy, benzyloxy, or hydroxy. *Id.*, *emphasis added*.

Essentially, Fujikawa's proposed sub-genus was directed to compounds in which R was cyclopropyl and R₀ was 4-fluorophenyl. The other particular constituents recited in Fujikawa's proposed count were adequately described in Wattanasin's application. *Id.*

The Board noted that Wattanasin preferred methyl and isopropyl for R, rather than cyclopropyl as in the proposed count. Additionally, it was noted that Wattanasin listed three preferred choices for R₀ only one of which was 4-fluorophenyl and gave no indication as to any preference between the three preferred choices. *Id.* The Board recognized that the compounds of the proposed count were not Wattanasin's preferred, and that his application contained insufficient "blazemarks" as to what compounds, other than those disclosed as preferred might be of special interest. Accordingly, the Board determined that in the absence of appropriate blazemarks, the mere disclosure of a large genus of compounds was not sufficient to satisfy the written description requirement as to a particular species or subgenuses. *Id.* at 1571, 39 USPQ2d at 1905.

The Federal Circuit affirmed. The court characterized the question raised in terms of whether Wattanasin's application provides adequate direction which reasonably would lead persons skilled in the art to the sub-genus of the proposed count. *Id.* at 1570, 39 USPQ2d at 1904.

With respect to Fujikawa's contention that Wattanasin mentioned each substituent recited in the proposed count, the Federal Circuit stated:

Clearly, however, just because a moiety is listed as one possible choice for one position does not mean there is *ipsis verbis* support for every species or sub-genus that chooses that moiety. Were this the case, a "laundry list" disclosure of every possible moiety for every possible position would constitute a written description of every species in the genus. This cannot be because such a disclosure would not "reasonably lead" those skilled in the art to any particular species. We therefore reject Fujikawa's argument on this point.

Id. at 1571, 39 USPQ2d at 1905. Additionally, the Federal Circuit noted that Fujikawa's proposed sub-genus diverged from Wattanasin's preferred elements. Specifically, the court stated:

As the Board pointed out, Fujikawa's proposed sub-genus diverges from Wattanasin's preferred elements at least with respect to position R. Although, in hindsight, the substitution of cyclopropyl for isopropyl might seem simple and foreseeable, **Wattanasin's disclosure provides no indication that position R would be a better candidate for substitution than any other.** Thus, faced with Wattanasin's disclosure, it was not clear error to hold that one of ordinary skill would not be led to Fujikawa's sub-genus in particular.

Id., emphasis added. Furthermore, the Federal Circuit compared Fujikawa's appeal to that recited in

*In re Ruschig*⁶ stating:

Were we to extend *Ruschig's* metaphor to this case, we would say that it is easy to bypass a tree in the forest, even one that lies close to the trail, unless the point at which one must leave the trail to find the tree is well marked. Wattanasin's preferred embodiments do blaze a trail through the forest; one that runs close by Fujikawa's proposed tree. His application, however, does not direct one to the proposed tree in particular, and does not teach the point at which one should leave the trail to find it.

Id.

⁶ 379 F.2d 990, 994-95, 154 USPQ 118, 122 (CCPA 1967).

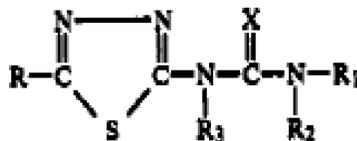
Fujikawa is consistent with the principle that description of a genus does not necessarily provide written description for a particular subgenus contained within the genus. In particular, *Fujikawa* was based upon a proposed subgenus which differed from at least one of the preferred moieties of the described genus. Indeed, the court was presented a subgenus which differed from the genus for at least *two* of the six variable moieties described, *i.e.*, R and R₀. Further, there was no indication that the moieties which differed between the described genus and the claimed subgenus would be better candidates for substitution than any others. It was upon such facts that the Court held that the Board did not err in finding that the proposed subgenus was not adequately described.

ii. *In re Driscoll*⁷

Driscoll involved an ex parte appeal from the Board which affirmed a rejection of Driscoll's claim 13. One issue on appeal involved Driscoll's claim for benefit of an earlier filing date based on a series of previously filed applications some of which were continuation-in-part applications. The Board determined that Driscoll was not entitled to the benefit of the filing dates of the earlier filed applications as the prior applications did not sufficiently describe Driscoll's claimed invention. *Id.* at 1246-47, 195 USPQ 435-436.

Driscoll's invention related to urea compounds which were described as useful in controlling undesired plant growth. Claim 13 of Driscoll, the specific claim on appeal, read as follows:

13. A compound of



⁷562 F.2d 1245, 195 USPQ 434 (CCPA 1977).

wherein R is alkylsulfonyl (C₁-C₆);

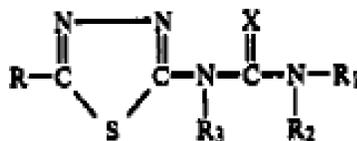
R₁ is selected from the group consisting of H, alkyl (C₁-C₄), and cycloalkyl (C₃-C₆);

R₂ is from the group consisting of H, alkyl (C₁-C₄), haloalkyl (C₁-C₄), alkoxy (C₁-C₄), alkenyl (C₂-C₄), alkynyl (C₂-C₄), aryl, and haloaryl, and wherein R₁ and R₂ are alkylene which, together with N, form a ring of at least 3, but not more than 6 members;

R₃ is H or alkyl (C₁₋₆); and X is selected from the group consisting of oxygen and sulfur.

As support for claim 13, Driscoll referred to the earlier applications describing a compound

having the following formula:



wherein R is selected from the group consisting of H, alkyl (C₁-C₆), haloalkyl (C₁-C₆), cycloalkyl (C₃-C₆), halocycloalkyl (C₃-C₆), alkoxy, alkoxyalkyl, alkoxyalkylthio, aryl, substituted aryl, alkenyl (C₂-C₆), alkylthio (C₁-C₆), alkylsulfoxide (C₁-C₆), and **alkylsulfonyl (C₁-C₆)**;

R₁ is selected from the group consisting of H, alkyl (C₁-C₄), and cycloalkyl (C₃-C₆);

R₂ is from the group consisting of H, alkyl (C₁-C₄), haloalkyl (C₁-C₄), alkoxy (C₁-C₄), alkenyl (C₂-C₄), alkynyl (C₂-C₄), aryl and haloaryl, and wherein R₁ and R₂ are alkyl which, together with N, form a ring of at least 3, but not more than 6 members;

R₃ is H or alkyl (C₁₋₆); and X is selected from the group consisting of oxygen and sulfur.

Id. at 1247, 195 USPQ at 435, emphasis added. Accordingly, it can be seen that the compound of claim 13 is the same as that previously described except claim 13 limited substituent R to just alkylsulfonyl (C₁-C₆).

The Board declined to grant Driscoll priority to the earlier filed application. Specifically, the Board concluded that:

In view of the relatively large number of possible values for R, and in the absence of anything in the disclosure to direct one specifically to the subgenus where R is alkylsulfonyl, we cannot agree with appellant's position.

Id. at 1248, 195 USPQ at 436.

The Court of Customs and Patent Appeals (CCPA), however, did not agree with the Board's analysis. In particular, the CCPA cited Driscoll's earlier applications as describing the claimed thiadiazole ureas as being particularly effective when containing an organic substituent in the 5-position of the thiadiazole portion.⁸ Thus, the CCPA reasoned that:

[T]he focus is unquestionably on the substituents at the 5-position of the thiadiazole moiety, and not on the substituents of the urea moiety. Accordingly, one skilled in the art would regard the structural formula of S.N.782,756 as signifying that no matter which member of the R group is present on the thiadiazole moiety, the urea moiety may be substituted or unsubstituted.

Id. at 1249, 195 USPQ at 437. Accordingly, it followed that the earlier formula described the subject matter of fourteen distinct classes of compounds including the one recited in Driscoll's claim 13. *Id.* at 1249, 195 USPQ at 437-438. Thus, the CCPA reasoned that the exact subgenus claimed was clearly discernable in the generalized formula of the earlier application. *Id.* at 1249, 195 USPQ at 438. Indeed, the Court made it clear that the Driscoll appeal involved a "hypertechnical application" of the written description requirement for which it was impossible to imagine any public purpose being served. *Id.*

⁸In other words, it did not matter to Driscoll what particular substituents were used for R¹, R², R³ and X so long as R was one of the defined Markush substituents.

The CCPA, however, warned against the generalization of its decisions in the area of written description. Specifically, the CCPA stated:

Moreover, it should be readily apparent from recent decisions of this court involving the question of compliance with the description requirement of § 112

that each case must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited.

Id. Accordingly, the decision in *Driscoll* reaffirms the factual nature of the written description requirement and that its assessment must be conducted on a case-by-case basis.

Unlike the facts of *Fujikawa*, *Driscoll*'s genus encompassed fourteen distinct classes of compounds from which one skilled in the art could readily discern the claimed subgenus. Specifically, the court in *Driscoll* was presented a generalized formula where one specific moiety, R, constituted the essence of the inventive subject matter.

iii. *In re Smith*⁹

Smith involved an ex parte appeal from the Board in which claims 1, 2, 12-18, 20 and 21 were held unpatentable. *Smith*'s claims were presented in a continuation-in-part application filed in 1965 which claimed priority to an application filed in 1947. In reviewing *Smith*'s claims, however, the Board determined that *Smith*'s claimed subgenus lacked adequate written description in the parent 1947 application. Accordingly, the Board did not accord *Smith* the benefit of the 1947 filing date under 35 U.S.C. § 120 and upheld the examiner's rejection under 35 U.S.C. § 103 which relied upon a 1948 U.S. patent.

⁹ 458 F.2d 1389, 173 USPQ 679 (1972).

Smith's invention was directed to a glossy water-based emulsion paint. According to Smith, prior art water-based paints tended to be "flat" in appearance. To provide a more glossy appearance, Smith's invention employed a pigment whose surface was coated in such a way that it would be wholly wetted by the oil phase of the emulsion and not permitted to migrate into the water phase. *Id.* at 1390, 173 USPQ at 679-680. Claim 1 of Smith read as follows:

1. An emulsion coating composition comprising essentially
a continuous aqueous phase and
a discontinuous water insoluble oil phase containing dispersed in said discontinuous phase a pigment which is surface coated with an organic compound effective to render said pigment oilphilic,
said organic compound being a monomeric organic compound characterized by **at least one** non-polar organic hydrophobic group containing **at least 8 carbon atoms** in a hydrocarbon structure, which group in the form of its monocarboxylic acid is soluble in oleoresinous varnishes and insoluble in water,
and at least one polar group,
said organic compound adhering to said pigment surface when said coated pigment is emulsified,
said coating having been applied to said pigment prior to emulsification thereof and prior to dispersion of said pigment in said oil phase,
and said discontinuous pigmented phase being capable of forming a continuous solid glossy film when dried.

Id. at 1390-91, 173 USPQ at 680, *emphasis added*.

As support for the claimed organic compound, Smith cited the following portion from the 1947 application:

The treatment of pigments with polar agents is not new per se and can be accomplished by several methods employing a variety of effective compounds. In general these methods involve surface coating the pigment with an oil soluble polar organic compound. Among the polar organic compounds are acidic resins, water soluble resins, water insoluble metallic resins, long chain fatty acids, their salts and soaps, benzene carboxylic acid and its salts, naphthenic acids and their soaps and salts, cationic active agents, e.g., alkyl amine salts and quaternary ammonium compounds containing at least 12 carbon atoms in an alkyl group or groups, e.g., lauryl pyridinium

bromide, and long chain (at least 12 carbon atoms) fatty acid-containing organic Werner complexes.

Id. at 1393-94, 173 USPQ at 682. Moreover, Smith stated that it would have been obvious to one skilled in the art that the organic compounds recited above are monomeric and have a hydrocarbon structure having at least 8 carbon atoms, except for the benzene carboxylic acid. From this, Smith asserted that the claimed invention is a subgenus of the 1947 description as the claims “delineate the invention more specifically.” *Id.*

In reviewing Smith’s 1947 application, the CCPA concluded that the mere disclosure of a genus and a species within a subgenus is not necessarily a sufficient description of the subgenus.

Specifically, the CCPA held that:

Precisely how close the description must come to comply with § 112 must be left to case-by-case development. . . . Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily always implicitly described by a genus encompassing it and a species upon which it reads.

Id. at 1395, 173 USPQ at 683. Further, the CCPA found nothing wrong with the principle that certain circumstances may operate to defeat the patentability of a narrow, but not a broader, claim. *Id.*

2. Shiokawa’s Earlier Applications are not a Constructive Reduction to Practice of the Subject Matter of Count 1

As recognized by Shiokawa, “in order to gain the benefit of the filing dates of its earlier filed applications for Count 1, Shiokawa must show that its parent U.S. applications and its foreign priority application each contains a constructive reduction to practice of Count 1.” (Shiokawa Corrected Preliminary Motion 1, Paper No. 74, p. 8). Shiokawa alleges a constructive reduction to practice of the subject matter of Count 1. Specifically, Shiokawa alleges that:

Claim 1 of the '146 patent is part of Count 1. Shiokawa will show that claim 1 is sufficiently described and enabled by each of the earlier-filed applications using the description of the preferred insecticides.

(Paper No. 74, p. 8). As the disclosure of each of the earlier filed JP and U.S. applications is substantively identical to that of the '146 patent, Shiokawa has focused on demonstrating that the '146 patent contains a sufficient written description of subject matter of Count 1.

As the moving party, Shiokawa bears the burden of proof. Shiokawa, however, has failed to meet its burden. Specifically, Shiokawa has failed to demonstrate that the '146 patent, and by extension its earlier JP and U.S. applications, constitutes a constructive reduction to practice of the subject matter of the count.

The '146 patent does not explicitly describe a 1,3,5-oxadiazine compound. Specifically, the '146 does not mention a 1,3,5-oxadiazine compound nor does the '146 patent depict a 1,3,5-oxadiazine structure. The '146 patent does, however, describe a genus of insecticidal heterocyclic compounds that broadly encompasses Shiokawa's claimed 1,3,5-oxadiazines. To satisfy the written description requirement the '146 patent must direct or guide one skilled in the art from the genus to the particularly claimed 1,3,5-oxadiazine subgenus. *Fujikawa*, 93 F.3d at 1571, 39 USPQ2d at 1905.

Using the blazemark metaphor of *Ruschig*, the '146 patent provides a map setting forth the boundaries of a forest. The '146 patent map describes numerous trails upon which the reader, one of ordinary skill in the art, may travel. The '146 patent even marks many of areas of the forest as "preferred." Additionally, the map identifies many individual trees and provides both general and specific guidance as to which paths the reader may follow to arrive at those trees. The map, however, does not identify the specific location of the claimed 1,3,5-oxadiazines. Yet, Shiokawa alleges that the

reader would, based upon various assumptions, know which trails to follow and where to jump off the trail in order to arrive at the location of the claimed 1,3,5-oxadiazines and would proceed to redraw the boundaries of the forest to set apart those general and preferred areas of the forest that fall within the claimed 1,3,5-oxadiazine subgenus.

Shiokawa has failed to convince us that the reader of the '146 patent map is directed or guided in such a fashion.

- i. Shiokawa's Claimed 1,3,5-Oxadiazine Subgenus is Narrower than Shiokawa's Genus and Both Broader and Narrower than Shiokawa's "Preferred" Subgenus

Shiokawa '146 provides a description of a genus and a preferred subgenus of insecticidal heterocyclic compounds. As shown below in Table I, the 1,3,5-oxadiazine compounds of Shiokawa '146 claim 1 differ from, and do not fall within, the preferred subgenus.

TABLE I

'146 PATENT COMPARISON OF CLAIM 1, PREFERRED GENUS AND GENUS 1			
Substituent of Formula 1	Claim 1	Preferred Genus	Genus
Z	-CH ₂ -O-CH ₂ -	three-membered straight chain, each member being selected from the group consisting of CH ₂ , O, S and N-R ² with at least one of said three members being O, S or N-R ²	three-membered straight chain, each member being selected from the group consisting of CH ₂ , O, S and N-R ² with at least one of said three members being O, S or N-R ²
E	N-R ²	N-R ²	N-R ²

		CH ₂	CH ₂
		O	O
		S	S
R ²	hydrogen atom		hydrogen atom
	C₁₋₄ alkyl group	C ₁₋₃ alkyl group	C₁₋₄ alkyl group

	2-chloropyridin-5-ylmethyl	2-chloropyridin-5-ylmethyl	heterocyclic nitrogen compound (see SX 2003, col. 1, lines 35-42)
		C ₁₋₃ alkoxy group	C ₁₋₄ alkoxy group

As apparent from Table 1, Shiokawa claim 1 is both narrower and broader than the preferred genus. The '146 patent, however, does not guide one skilled in the art to make the selections that are required to arrive at the subject matter of claim 1.

ii. Shiokawa Makes Numerous Assumptions in Order to Demonstrate that the '146 Patent Guides One Skilled in the Art to the Claimed 1,3,5-Oxadiazines

Shiokawa contends that claim 1 of the '146 patent is sufficiently described and enabled such that claim 1 is a constructive reduction to practice of the subject matter of the count. In making this argument Shiokawa's Preliminary Motion 1 and Dr. Pearson's supporting declaration testimony (SX 2001) subject one skilled in the art to an intricate and imaginative combination of assumptions that are more akin to a labyrinth than a well marked path. For example, Shiokawa and Dr. Pearson make the following assumptions:

- (1) One skilled in the art would focus on the Z group and would "most likely" have begun generating compounds having one oxygen atom and repeat the procedure with a sulfur and N-R² group for Z. (Paper No. 75, pages 13-14 and SX 2001, ¶27).

(2) Focusing on the heterocycles assembled from acyclic reactants,¹⁰ one skilled in the art would have seen that N-R² is preferred in the E position since nitroguanidine and cyanoguanidine are the only acyclic reactants used in the '146 patent. (Paper No. 75, page 15 and SX 2001, ¶28).

(3) That 1,3,5-oxadiazine, 1,3,5-thiadiazine and 1,3,5-triazines are fundamentally related in that they may be produced by condensation reactions of formaldehyde with H-B-H where B is O, S or N-R² (i.e. H₂O, H₂S and H₂NR²) and nitroguanidine or cyanoguanidine. (Paper No. 75, pages 16-17 and SX 2001, ¶28).¹¹

(4) The '146 patent teaches the interchangeability of -CH₂-O-CH₂-, -CH₂-S-CH₂- and -CH₂-N(R²)-CH₂-. (Paper No. 74, page 19, SX 2001, ¶32).

¹⁰Note, the 3-cyano-iminomorpholine and the 3-nitroiminomorpholine heterocyclic compounds described at col. 2, line 55 to col. 3, line 35, exemplified in example 1 and depicted in compounds 1-9 do not require assembly of the core heterocycle from acyclic reactants.

¹¹Note, Dr. Pearson specifically testifies that:

A person of ordinary skill in the art of heterocyclic chemistry in the 1988-90 time frame knew that production of 1,3,5-oxadiazines could occur without any external nucleophile like water. Only the formaldehyde, a guanidine, and an acidic environment are needed. 1,3,5-oxadiazines have been synthesized under non-aqueous conditions (from a urea, paraformaldehyde with an acid catalyst in chloroform) by Seidel et al. SX 2052.

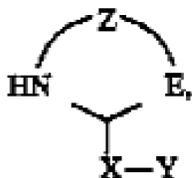
(SX 2001, ¶41, emphasis added). Additionally, Dr. Pearson testifies that:

“It should also be noted that the work of Seidel and Boettner shows that the synthesis of oxadiazines using this method is simpler than the synthesis of thiadiazines, since the oxadiazine preparation requires only the thiourea and paraformaldehyde (a source of formaldehyde), whereas the thiadiazine preparation requires the additional presence of (H₂S).” (SX 2001, ¶32, emphasis added).

Even assuming that all of the above assumptions are correct, Shiokawa has failed to demonstrate that the '146 patent reasonably conveys to those skilled in the art that Shiokawa invented the claimed 1,3,5-oxadiazine compounds. Rather, if correct, the above assumptions may demonstrate that the claimed 1,3,5-oxadiazines would have been obvious to one skilled in the art. Specifically, the assumptions may further demonstrate that one skilled in the art may have been motivated to form the claimed 1,3,5-oxadiazines with the reasonable expectation that they would function as effective insecticidal compounds.

iii. Shiokawa's Assumptions Evidence Obviousness Not Written Description

Shiokawa's assumptions, if correct, do not establish that one skilled in the art would understand that Shiokawa invented the claimed 1,3,5-oxadiazine compounds. For instance, Shiokawa has chosen to focus on the Z group of the heterocycles formed from the acyclic reactants mentioned in the '146 patent, i.e., Shiokawa attempts to direct our attention to the intermediate 1,3,5-triazine heterocycles of col. 3, lines 35-53, several of which were prepared in examples 5-7. Taken as a whole, however, the '146 patent teaches that the insecticidal heterocyclic compounds of the invention are obtained from heterocyclic compounds of formula (III) depicted below:



(SX 2003, col. 1, lines 18-63). The '146 patent specifically names three intermediate heterocyclic structures encompassed by formula (III) (3-cyano-iminomorpholine, 3-nitroiminomorpholine, and, 1,3,5-triazine) and how they can be obtained. (SX 2003, col. 2, line 55 to col. 3, line 53 and examples 1 and 5-7). Furthermore, the compounds depicted in Table 1 of the '146 patent would be formed from the three named intermediate heterocycles as well as from others. With the exception of those falling within the preferred subgenus, the '146 patent does not identify the named, exemplified or depicted intermediate heterocycles as preferred. Furthermore, as noted above, the only exemplified intermediate heterocycle that specifically formed a "preferred" compound of the invention was the 3-cyanomorpholine described in example 1. Thus, while it may have been obvious to select the 1,3,5-triazine heterocycles of formula (III) and modify them using the assumptions set forth in Shiokawa's Corrected Preliminary Motion 1 with the expectation that the resultant compound would possess insecticidal properties, the '146 patent itself does not guide or direct one skilled in the art to make that particular selection.

As explained in *Lockwood*, entitlement to a filing date does not extend to subject matter which is not disclosed, but would have been obvious over what is expressly disclosed. *Lockwood*, 107 F.3d at 1571, 41 USPQ2d at 1966. The following discussion provides a glimpse at the number of assumptions that Shiokawa alleges one skilled in the art would "implicitly" find in the '146 patent. For example, Shiokawa assumes that one skilled in the art would be implicitly directed to focus upon the Z group of the described insecticidal heterocyclic compounds as opposed to the A, R¹, E, X and Y moieties. Shiokawa also assumes that one skilled in the art would then be implicitly guided to generate those compounds where Z is formed from two methyls and one heteroatom or heterogroup, O, S, or N-R² as opposed to those compounds where Z is formed from two or three heteroatoms or

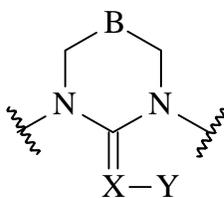
heterogroups. Moreover, in generating the identified Z compounds, one would choose to focus on those heterocycles assembled from the described acyclic reactants as opposed to the described the iminomorpholine heterocyclic compounds described at col. 2, line 55 to col. 3, line 35, and employed in the first example of the '146 patent. Having focused on the acyclic reactant produced heterocycles, one skilled in the art would then understand that since 1,3,5-oxadiazine, 1,3,5-thiadiazine and 1,3,5-triazines differ in only one specific reactant, that the compounds are fundamentally related. One skilled in the art would also understand that "at least one of said three members being O, S and N-R²" guides one skilled in the art to the conclusion that -CH₂-O-CH₂-, -CH₂-S-CH₂- and -CH₂-N(R²)-CH₂- are interchangeable and that possession of a 1,3,5-triazine intermediate compound conveys that Shiokawa invented the claimed 1,3,5-oxadiazine subgenus. Further, Shiokawa assumes that one skilled in the art would be guided to "pick and choose" the claimed R² members (H, C₁₋₄ alkyl and 2-chloropyridin-5-ylmethyl) from among the R² members of the genus and preferred subgenus.¹² We are not convinced that the '146 patent directs or guides one skilled in the art to make these assumptions.

¹²The '146 patent does not mention the specific definition of the R² moiety as it is presented in claim 1. We note that originally filed claim 1 defined R² group as representing a hydrogen atom, a C₁₋₄ alkyl group, a C₁₋₄ alkoxy or a specific class of aromatic compounds. (SX 2037, p. 35). Originally filed claim 2 defined the R² group as representing a C₁₋₃ alkyl group, a C₁₋₃ alkoxy group or 2-chloropyridin-5-ylmethyl. Additionally, we note that claim 15, added in a preliminary amendment (SX 2006), defined the R² group as "a hydrogen atom or a C₁₋₄ alkyl group." Claims 1, 2 and 15 were rejected by the examiner under 35 U.S.C. § 112 first and second paragraphs. (SX 2007, pages 6-7). Shiokawa, among other things, added new claim 18 in an amendment responding to the examiner's office action. (SX 2037, pages 132-133). Claim 18 seems to be the first appearance of the specific definition of the R² moiety as it presented in claim 1 of the '146 patent.

iv. Many of Shiokawa's Assumptions Regarding the Guidance Provided by the '146 Patent are Unsupported

Shiokawa attempts to lead us away from the plain language of the '146 patent with assumptions that are based primarily upon unsupported declaration testimony. For example, Shiokawa repeatedly directs our attention to Dr. Pearson's declaration testimony as support for their assumptions regarding the guidance provided by the '146 patent. Nothing in our rules or in our jurisprudence, however, requires us to credit the unsupported assertions of an expert witness. *Cf. Rohm & Hass Co. v. Brotech Corp.*, 127 F.3d 1089, 1092, 44 USPQ2d 1459 (Fed. Cir. 1997).

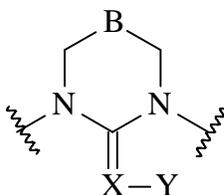
There are many instances where Shiokawa's statements and Dr. Pearson's declaration testimony appear unsupported by the evidence. For instance, Shiokawa and Dr. Pearson fail to identify sufficient evidentiary support for: (1) why one skilled in the art would be directed to classify the compounds of Table 1 into their "core-heterocycle" groups; (2) how the '146 patent guides one skilled in the art to classify the "core-heterocycles" of Table 1 into four groups with Group I being:



where B is O, S, or N-R²,¹³ and, (3) the conclusion that since certain heterocycles of Group I appear in the examples and Table 1 of the '146 patent, Shiokawa has demonstrated a clear preference for the compounds of Group I. (SX 2001, ¶¶16-25).

The '146 patent does not appear to state that the Z group or E group constituted the essence of the inventive insecticidal heterocyclic compounds. Indeed, the '146 patent is silent as to the effects of each of the individual substituents that are allowed to vary, i.e., A, R¹, Z, E, X and Y, upon the heterocyclic insecticidal compounds of the invention. Further, the '146 patent does not appear to recite a "special interest" in the Z group or the E group. Shiokawa has failed to demonstrate that the plain language of the '146 patent directs one skilled in the art to the classify the heterocycles of Table 1, based upon their definitions of Z and E, into "core-heterocycle" groups.

Similarly, we find no reason to disagree with Maienfisch's assertion that the '146 patent does not appear to classify the 40 compounds of Table 1 into four core-heterocycle groups with Group I represented by the formula:



¹³Note, Shiokawa's core-heterocycles of Groups II, III and IV do not appear to possess the same "interchangeability" as that of Group I where the heteroatom or heterogroup is O, S or NR². Specifically, Groups II and III are directed to heterocycles having 2 methyl groups (CH₂) and one oxygen heteroatom. Furthermore, Group IV is a heterocycle having 2 methyl groups and a moiety Q which is defined as oxygen or NH. Shiokawa has failed to sufficiently explain why the interchangeability of Group I differs from that of Groups II-IV.

where B is O, S, or N-R² and E is a nitrogen group. The '146 patent does not seem to mention a "special interest" in the Z group or identify compounds where Z is -CH₂-O-CH₂-, -CH₂-S-CH₂- and -CH₂-N(R²)-CH₂- as representing a specific class of compounds. Nor does the '146 patent mention a preference for those compounds having an N(R²) group for E as opposed to a CH₂, O or S moiety. Shiokawa, and Dr. Pearson, have failed to sufficiently identify the guidance provided in the '146 patent that leads to the proposed classification scheme.

Additionally, Dr. Pearson has explicitly represented that the '146 patent teaches one skilled in the art that "the heteroatoms or heterogroups CH₂, O, S, or N-R² are interchangeable" in the *E* position. (SX 2001, ¶17).¹⁴ Yet, substituting CH₂, O, S for the N-R² moiety in Group I leads to compounds outside the scope of Shiokawa's claims. Thus, if Dr. Pearson's "interchangeability" of E were correct, one skilled in the art would not necessarily be directed to the claimed 1,3,5-oxadiazines where E is N-R².

¹⁴During cross-examination deposition, Dr. Pearson testified that:

Right below that there is another generic structure. This is in the middle-right of Table 1 [p. 9 of Dr. Pearson's Declaration SX 2001], where E, again, would be oxygen. I don't think that the '146 patent provides enough information to make such a compound, and based on the literature that I am familiar with, I would like to say there may be some really great way to do this out there that I don't know, but sitting here today, I doubt that there is a compelling body of literature that would lead me to believe that compound is implicitly described.

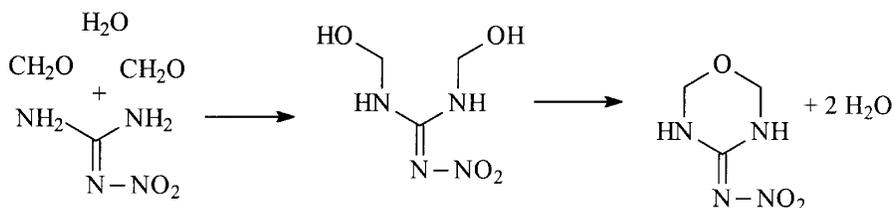
(MX 1037, Deposition of Dr. Pearson, p. 124). Thus, according to Dr. Pearson, replacing one E substituent with another E substituent can lead to compounds that one skilled in the art may be unable to synthesize.

Shiokawa has assumed that the “interchangeability” of the heteroatoms and heterogroups of the Z group is the interchangeability within the group of O, S, or N-R². The ‘146 patent, however, explicitly states “*at least one* of said three members” for Z is O, S, or N-R², and thus, explicitly leads one skilled in the art to also contemplate more than heteroatom or heterogroup. Accordingly, the “interchangeability” noted by Shiokawa would, following the plain language of the ‘146 patent, lead one skilled in the art to replace the CH₂ moieties appearing in the Z position of the “core-heterocycle” groups with O, S, or N-R² so long as the resulting compound contained at least one O, S, or N-R² in the Z position. Yet, the ‘146 patent cannot be said to lead one skilled in the art to the Shiokawa Group I heterocycles if one skilled in the art is allow to freely change the Z group CH₂, O, S, or N-R² such that the final heterocycle contains at least one of O, S, or N-R² in the Z position.

Shiokawa contends that since certain heterocycles of Group I appear in the examples and Table 1 of the ‘146 patent, there exists a “clear preference” for the compounds of Group I. (SX 2001, ¶¶16-25). The ‘146 patent, however, makes no such statement. Moreover, the examples and Table 1 of the ‘146 patent are not directed to a 1,3,5-oxadiazine compound. Also, none of the examples and only one of the forty compounds of Table 1 involves a 1,3,5-thiadiazine compound. As such, it is not clear that the ‘146 patent evidences, as alleged by Shiokawa, a “clear preference” for compounds possessing the 1,3,5-oxadiazine or 1,3,5-thiadiazine ring structure encompassed by Shiokawa’s Group I.

- v. Example 5 of the ‘146 Patent does not Reasonably Convey that Shiokawa Invented Claimed 1,3,5-oxadiazines

Shiokawa states that a 1,3,5-oxadiazine is inherently produced by following the cyclization process of Example 5 of the '146 patent. According to Shiokawa, this "fact is established in the declaration testimony of Dr. Peter Jeschke. SX 2056." (Shiokawa Corrected Preliminary Motion 1, Paper No. 74, p. 10). Shiokawa alleges that a person of ordinary skill in the art would have recognized "the likelihood" that a 1,3,5-oxadiazine would be co-produced in working example 5. (Paper No. 74, p. 23). Moreover, Shiokawa states that one skilled in the art would understand that a 1,3,5-oxadiazine is produced during the reaction described in Example 5 as follows:



(Paper No. 74, p. 24).

Shiokawa contends that the "inherent" formation of a 1,3,5-oxadiazine compound in example 5 of the '146 patent is a "blazemark" demonstrating sufficient written description for its claims 1,3,5-oxadiazine subgenus. Yet, Shiokawa has not demonstrated that a 1,3,5-oxadiazine intermediate compound is "inherently" present in the resulting product of the reaction of example 5. Inherency is not established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to demonstrate inherency. *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). Thus, in order to demonstrate that a 1,3,5-oxadiazine intermediate compound was formed in example 5 of the '146 patent, Shiokawa needs to demonstrate that a 1,3,5-oxadiazine compound would necessarily be present in the final product of example 5.

Example 5 makes no mention as to the coproduction of a 1,3,5-oxadiazine intermediate compound. Example 5 is entitled “Preparation of an intermediate compound” and depicts the structure of a 1,3,5-triazine compound (5-methoxy-2-nitroimino-hexahydro-1,3,5-triazine) that conforms to the intermediate heterocycles of formula (III). (SX 2003, col. 17, lines 25-35). Example 5 provides a mixture of nitroguanidine, methoxyamine hydrochloride, paraformaldehyde, toluene and a catalytic amount of hydrochloric acid. (SX 2003, col. 17, lines 37-40). There is no dispute that this mixture is capable of reacting to form the 5-methoxy-2-nitroimino-hexahydro-1,3,5-triazine said to have been obtained in example 5.

Attempting to prove inherency, Shiokawa relies upon an experiment said to have been conducted by Dr. Peter Jeschke where Dr. Jeschke attempted to carry out the reaction described in example 5 of the ‘146 patent. (SX 2056, p. 2). It is not clear that Dr. Jeschke successfully replicated example 5. For example, after removing the solvent, Dr. Jeschke obtained a “light *yellow* solid” whereas example 5 of the ‘146 patent was said to have obtained “*white* crystals.” (SX 2003, col. 17, lines 43-47). Shiokawa, however, has not sufficiently explained why Dr. Jeschke obtained a yellow product as opposed to the specifically stated white product of example 5. As the resulting products of Dr. Jeschke’s process and that of example 5 differed in color, Shiokawa has failed to demonstrate that the final product of example 5 would necessarily contain a 1,3,5-oxadiazine.

Additionally, there is no indication that the Shiokawa inventors were aware that a 1,3,5-oxadiazine intermediate compound was potentially formed by the process of example 5. At best, Shiokawa has demonstrated that it may be theoretically possible for a detectable quantity of a 1,3,5-oxadiazine intermediate compound to form in the reaction of example 5. Yet, the mere

demonstration that one skilled in the art would understand that there is a possibility that a detectable amount of a 1,3,5-oxadiazine might be present in the product of a reaction that was specifically designed to produce 5-methoxy-2-nitroimino-hexahydro-1,3,5-triazine, and which actually produces 5-methoxy-2-nitroimino-hexahydro-1,3,5-triazine, does not reasonably convey to one skilled in the art that the inventors had invented the potentially “coproduced” 1,3,5-oxadiazine intermediate.

vi. Shiokawa Had Role in Creation of 1,3,5-Oxadiazine Claims

Shiokawa alleges that “[t]he only reason the ‘146 patent is limited to 1,3,5-oxadiazines is because of the examiner’s rigid approach to restriction that is based on structural characteristics only, *without regard to the disclosed biological properties of the compounds*. (Shiokawa Corrected Preliminary Motion 1, p. 9, emphasis in original). Moreover, Shiokawa states that:

A patent applicant cannot know exactly how the PTO will choose to restrict the generic claims, a requirement made to simplify the examiner’s work load in a given case. Sometimes no generic formula in the specification corresponds exactly to the claims allowed after restriction.

(Shiokawa Corrected Preliminary Motion 1, pp. 24-25).

Shiokawa has failed to demonstrate that an examiner’s restriction requirement is relevant to the fact based determination of whether the ‘146 patent contains an adequate written description of the claimed 1,3,5-oxadiazines. Specifically, Shiokawa has not identified any plausible connection between the examiner’s restriction requirement and their addition of claims to an unsupported invention. Nor are we aware of any such connection.

Additionally, Shiokawa conveniently overlooks their role in the creation and patenting of the 1,3,5-oxadiazine claims. During the prosecution of the ‘780 application (‘146 patent), the examiner

issued a restriction requirement. (SX 2005, Office Action mailed June 27, 1996, p. 5). The restriction requirement identified five distinct groups of inventions. The restriction did not identify 1,3,5-oxadiazines as one of the independent and distinct inventions, rather the 1,3,5-oxadiazines fell into the fifth group which encompassed “any other species instance in claim 1 not grouped above.” (SX 2005, p. 2). In response to the restriction requirement, Shiokawa decided to provisionally elect, with traverse, the 1,3,5-oxadiazines compounds, *a subgenus not specifically identified by the examiner in the restriction requirement*. (SX 2005, pages 2 and 5).

vii. Lack of Written Description Finding is Consistent with Statement Made by Several of the ‘146 Inventors

Our analysis is consistent with that of several of the inventors named in the ‘146 patent. Specifically, Japanese Application No. 6-35254 (laid open no. 7-224062) was filed on February 9, 1994 (‘254 application”). Koichi Moriya and Yumi Hattori are listed as inventors on both the ‘254 application and the ‘146 patent. (Compare SX 2003, front page and MX 1005, p. 1). The JP ‘254 application specifically describes both 1,3,5-oxadiazines and 1,3,5-thiadiazines, i.e., X is oxygen or sulfur in Formula (I). (MX 1005, p. 4). Indeed, claim 2 of the ‘254 application is directed to 1,3,5-oxadiazines that are fully encompassed by the subgenus of claim 1 of the ‘146 patent.¹⁵ Yet, the JP ‘254 application states:

PRIOR ART AND TECHNICAL ISSUES Laid-open Patent Application Hei 2-235881 [i.e., JP application ‘943, the foreign priority document relied upon by the ‘146 patent], which was known prior to the submission of this application, describes nitro or

¹⁵Note that claim 2 of the JP ‘254 application defines A as including 6-chloro-3-pyridyl whereas claim 1 of the ‘146 patent defines A as including 2-chloropyridin-5-yl. While named differently, these are the same substituents.

cyano compounds. *The compounds of the present invention's application can be conceptually included in the [JP '943] disclosure, but are not specifically disclosed therein.*

(MX 1005, p. 3, emphasis added). Thus, our analysis as to the '146 patent's lack of written descriptive support for the claimed 1,3,5-oxadiazines is not inconsistent with the comments made by several of the inventors of the '146 patent.

C. Maienfisch Preliminary Motion 1 Alleging Lack of Written Description for Claims of '146 Patent

Maienfisch Preliminary Motion 1 moves for judgement against claims 1-3 of the '146 patent on the grounds that the application for the '146 patent did not contain a written description of the claimed invention. Maienfisch's motion raises many issues similar to those addressed above with respect to Shiokawa's Corrected Preliminary Motion 1,^{16, 17} especially since Shiokawa's arguments regarding their alleged constructive reduction to practice of the subject matter of the count were directed to the question of written description for claim 1 of the '146 patent. Rather than repeat many of the arguments raised by the parties with respect to Maienfisch Preliminary Motion 1, we focus on those

¹⁶As the moving party of Maienfisch Preliminary Motion 1, Maienfisch bears the burden of proof on the issue of Shiokawa's lack of written description for claims 1-3 of the '146 patent.

¹⁷Regarding the lack of written description for claims 1-3 of the '146 patent, we review the written description contained in Shiokawa's '780 application as of its February 7, 1996 filing date as opposed to Shiokawa's earlier filed applications.

arguments which appear to have been primarily raised by Shiokawa in its Opposition 1 and not in its Corrected Preliminary Motion 1.¹⁸

1. Shiokawa Mischaracterizes the Decision in *Fujikawa*

Shiokawa attempts to distinguish the case law relied upon by Maienfisch. In particular, Shiokawa argues that:

[I]n the opinions cited by Maienfisch, there is no indication that the party for which benefit was denied had contested whether the count defined a separate patentable invention from the invention that it had disclosed. That is, in contrast to Shiokawa Motion No. 5, no motion to substitute a broader count for the original count of the interference was filed. Thus, there is an element of estoppel in all of those opinions. The rationale for estoppel is explicitly stated in an opinion that Maienfisch did not cite, but which is the foundation for the interference opinions that Maienfisch did cite. That opinion is Bigham v. Godfredsen, 857 F.2d 1415, 8 USPQ2d 1266 (Fed. Cir. 1988).

(Paper No. 81, Shiokawa Opposition 1, p. 7, footnote omitted). After discussing the facts and holding of *Bigham*, Shiokawa makes the following statement regarding the decision in *Fujikawa*:

Similarly, in Fujikawa v. Wattanasin, 93 F.3d 1559, 39 USPQ2d 1895 (Fed. Cir. 1996), Wattanasin sought to substitute for the original broad count a narrow count reciting subject matter that it did not adequately describe. 93 F.3d at 1569-70, 39 USPQ2d at 1904-05.

(Paper No. 81, p. 8).

The “element of estoppel” discussed in *Bigham* plays no part in our understanding of the *Fujikawa* decision which is relied upon by Maienfisch. Specifically, the decision in *Fujikawa* did not involve a party asserting contradictory conclusions of law, i.e., that specific compounds form both the

¹⁸We note that Shiokawa Reply 1 and Shiokawa Opposition 1 and the arguments contained therein have been fully considered but do not alter our denial of Shiokawa’s Corrected Preliminary Motion 1.

same and separate patentable inventions. Indeed, Shiokawa erroneously states the facts and reasoning set forth in *Fujikawa*. In *Fujikawa*, **Fujikawa** filed a motion to add a narrow subgenus count and it was **Wattanasin**'s disclosure that did not sufficiently describe the subject matter of the proposed count. The court made no mention of an estoppel theory in determining that Wattanasin's disclosure lacked adequate written description for the proposed subgenus count. It does not stand to reason that the court meant to imply that *Fujikawa*'s motion estopped Wattanasin from asserting adequate written descriptive support for the proposed subgenus.

2. Dr. Ziegler's Testimony Does Not Establish Presence of 1,3,5-oxadiazine in Final Product of Example 5

Shiokawa contends that Dr. Ziegler, Maienfisch's expert, conceded that a 1,3,5-oxadiazine should be considered among the products formed in the reaction mixture of example 5. (Paper No. 81, p. 10 and SX 2086). While it appears that Dr. Ziegler could not rule out the possibility that a 1,3,5-oxadiazine could be formed using the nitroguanidine and paraformaldehyde of example 5, it is not clear that Dr. Ziegler admits that a 1,3,5-oxadiazine would be present in the final product of example 5. Specifically, Dr. Ziegler's depiction of the products of example 5 (SX 2086) appears directed to example 5 of the '146 patent with the methoxyamine hydrochloride (amine reactant) being specifically omitted from the reaction mixture. Similarly, the question asked of Dr. Ziegler during his cross-examination included the statement "the 1,3,5-oxadiazine was one of the possible products following example 5 but omitting the amine reactant." While the omission of the amine reactant may result in the formation of the 1,3,5-oxadiazine the focus of example 5 is a reaction where methoxyamine

hydrochloride is present. Additionally, we note that the Peterson reference (SX 2051) cited by Shiokawa specifically teaches a reaction of a 1,3,5-oxadiazine compound and a hydrochloride salt of a methyl amine. (SX 2051, p. 247). As it is possible that a 1,3,5-oxadiazine would react with the methoxyamine hydrochloride of example 5, we cannot construe the identified testimony of Dr. Ziegler as affirmatively conceding that the 1,3,5-oxadiazine was a possible end-product of example 5.

3. *In re Driscoll* is Readily Distinguish From the Facts of this Interference

According to Shiokawa, the facts of this case are close to those in *In re Driscoll*. According to Shiokawa, the heteroatom Z is selected from the group consisting of O, S and N, making all three of the symmetrical “core” heterocycles clearly discernible in the general formula of the ‘146 patent. (Paper No. 81, p. 11).

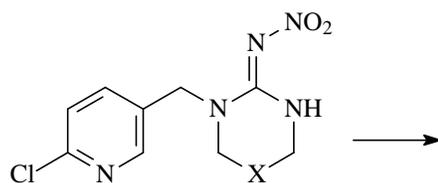
The court in *Driscoll* was presented a generalized formula where one specific moiety, R, constituted the essence of the inventive subject matter. Specifically, the application in question stated that: “Particularly effective [herbicides] are [thiadiazole ureas] which contain an organic substituent in the 5-position of the thiadiazole portion.” *In re Driscoll*, 562 F.2d at 1249, 195 USPQ at 437. The court determined that the focus of Driscoll’s application was unquestionably on the substituents at the 5-position of the thiadiazole moiety, and not on the other substituents present in Driscoll’s genus of herbicidal compounds.

Unlike the facts of *In re Driscoll*, ‘146 patent does not recite a special interest in a particular variable for its generalized formula. Moreover, the ‘146 patent does not identify the Z position or E

position as the focus of the insecticidal heterocyclic compounds. Specifically, in contrast to the facts of *In re Driscoll*, Shiokawa has failed to demonstrate that the plain language of the '146 patent directs one skilled in the art to the particular Z or E groups as the focus of the invention such that each of the various possible permutations for the Z group and E group is described by the '146 patent. Moreover, the '146 patent does not direct one skilled in the art to focus upon those heterocycles possessing a symmetrical core, e.g., -N-CH₂-B-CH₂-N- where B is O, S or N-R².

4. Maienfisch's Published Abstract Does Not Evidence the Shiokawa's Possession of the 1,3,5-oxadiazines

Shiokawa contends that Dr. Maienfisch published an abstract having the following formula:



X = NR, O, S
Novartis & others (>1989)

(Paper No. 81, p.22 and SX 2083). According to Shiokawa, this formula and caption demonstrate that "Maienfisch concedes that the specifications of the involved Shiokawa '146 patent and its equivalent foreign counterparts disclose O and S heteroatoms in the middle of the Z chain." (Paper No. 81, p. 22).

The depicted formula and caption do not demonstrate a concession by Dr. Maienfisch that the '146 patent describes O and S in the middle position of the Z-chain. At best, the formula and corresponding caption show that sometime after 1989, i.e., >1989, Novartis and others were aware of the depicted compound. It is not clear that the reference to "others" in the caption is a reference to the inventors of the '146 patent. Further, it is not clear that the reference to >1989 refers to the publication of Shiokawa JP '943 as opposed to the filing of Maienfisch's EP 483,055 Swiss priority document and/or the later filed Maienfisch '664 disclosure. The depicted formula and caption do not demonstrate that the '146 patent directed one skilled in the art to the claimed 1,3,5-oxadiazines.

D. Shiokawa Preliminary Motion 4 that Maienfisch's Claims are Unpatentable over Prior Art

Shiokawa's Japanese patent application JP 1-54943 ("JP '943") was published on September 18, 1990 and is available as prior art under 35 U.S.C. 102(b) as to Maienfisch's U.S. 09/136,664 application.¹⁹ JP '943 describes heterocyclic compounds and insecticidal compositions and methods employing the heterocyclic compounds as the active component. (Certified Translation of JP '493, SX 2023, pages 1-3). Maienfisch's claimed compounds, with the exception of the tautomers, fall within the literal scope of the heterocyclic compounds described by JP '943 and a majority of Maienfisch's

¹⁹Shiokawa also contends that Maienfisch '664 is unpatentable over Shiokawa U.S. Patent No. 5,032,589. (Shiokawa Preliminary Motion 4, Paper No. 37, p. 1). Shiokawa's U.S. Patent and laid open JP publication are "substantively identical." (Shiokawa Preliminary Motion 4, p. 2). As the disclosures of the two documents are substantively identical we discuss the patentability of Maienfisch '664 with respect to Shiokawa's laid open JP publication with the understanding that the analysis would be the same as that for Shiokawa's 5,032,589 patent.

claimed compounds fall within the scope of the preferred heterocyclic compounds of JP '943.

Similarly, Maienfisch's claimed compositions and methods, with the exception of the tautomers, fall within the scope of compositions and methods described by JP '943. JP '943, however, does not literally describe a 1,3,5-oxadiazine heterocyclic compound nor would such a compound be immediately envisioned from the JP '943 disclosure. Yet, the JP '943 disclosure does suggest that certain classes of heterocyclic compounds, such as Maienfisch's claimed oxadiazines, would be effective as insecticides.

Thus, given the JP '943 disclosure, it may have been *prima facie* obvious to one of ordinary skill in the art to form Maienfisch's claimed 1,3,5 oxadiazines with the expectation that such compounds would function as effective insecticides.

Additionally, we note that Maienfisch's parent '931 application specifically claimed a pest-resistant plant propagation material having 1,3,5-oxadiazines. The claimed 1,3,5-oxadiazine containing material was rejected as obvious over Shiokawa's parent '589 patent. (SX 2063, pages 3-4). In making the obviousness rejection the examiner stated that:

It is noted that the closest compound disclosed in Shiokawa is compound no. 23 at Col. 13. The claimed compounds differ from this compound only by the replacement of the sulfur ring atom with an oxygen atom. These two atoms are taught to be equivalent at this position at Col. 1, line 30 in the formula I compounds. Thus, one skilled in the art would have been motivated to replace the sulfur atom with an equivalent oxygen atom with the expectation that such similar compounds would possess similar insecticidal activity.

If applicants intend to present evidence of unexpected insecticidal results, such testing should be comparative with closest compound in Shiokawa, i.e. compound 23 therein.

(SX 2063, p. 4).

A party rebutting an assertion of obviousness may present comparative test data showing that the claimed compounds possesses unexpectedly improved properties or properties not possessed prior art compounds. *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995). As set forth in *In re Soni*:

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. The basic principle behind this rule is straightforward -- that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious. The principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results.

54 F.3d at 750, 34 USPQ2d at 1687. Moreover, given a presumption of similar properties for similar compositions, substantially improved properties are *ipso facto* unexpected. 54 F.3d at 751, 34 USPQ2d at 1688. Unexpected results must be shown to be unexpected compared with the closest prior art. *In re Baxter Travenol Labs*, 952 F.2d 388, 392, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991). Furthermore, in order to establish unexpected results for a claimed invention, objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support. *In re Clemens*, 622 F.2d 1029, 1035, 206 USPQ 289, 296 (CCPA 1980).

Maienfisch has submitted evidence to demonstrate that their presently claimed 1,3,5-oxadiazines have unexpectedly superior insecticidal properties as compared to the closest comparable compounds recited in JP ‘943. Specifically, Maienfisch relies upon a Declaration of Dr. Hubert Buholzer, dated July 28, 1998 (SX 2008), as well as a Declaration of Alfred Rindlisbacher,

dated October 6, 2000 (MX 1034), as demonstrating the unexpectedly superior properties of Maienfisch's claimed 1,3,5-oxadiazines.

Dr. Hubert Buholzer's declaration testimony (SX 2008) provides a discussion of a test where compound 23 of the '146 patent (a 1,3,5-thiadiazine) was compared against a 1,3,5-oxadiazine compound whose molecular structure differed from compound 23 only in that an oxygen atom replaced the sulfur atom. The 1,3,5-oxadiazine compound is encompassed by Maienfisch claim 24. The two compounds were tested at several different concentrations against a variety of pests. In each instance, the 1,3,5-oxadiazine compound provided equivalent or superior insecticidal action. (SX 2008, tables 1 and 2). According to Dr. Buholzer, the superior insecticidal action of the 1,3,5-oxadiazine compound was highly surprising and could not have been expected from the teachings of the prior art. (SX 2008, p. 5).

The declaration testimony of Mr. Alfred Rindlisbacher reviews the test data, Annex 23 and Annex 24, that was submitted by Novartis in connection with a European patent opposition proceeding relating to EP 386,565. (MX 1034, p. 1). According to Mr. Rindlisbacher, the Annex 23 data is from a battery of tests performed by Mr. Rindlisbacher for a variety of compounds. (MX 1034, p. 2). Mr. Rindlisbacher testifies that of the forty compounds depicted in Table 1 of the '146 patent, eight were tested along with their closest 1,3,5-oxadiazine analogs for insecticidal effectiveness. (MX 1034, pages 23-24). A comparison of the insecticidal test results for the eight compounds from the '146 patent and their closest 1,3,5-oxadiazines is provided in Table 19 of Mr. Rindlisbacher declaration. (MX 1034, p. 24). The eight compounds from the '146 patent included one "nitro"-1,3,5-thiadiazine (compound 23), six "nitro"-1,3,5-triazines (compounds 11,12, 14, 15,16 and 19) and one "cyano"-1,3,5-triazine

(compound 17). As evident from Mr. Rindlisbacher's Table 19, the 1,3,5-oxadiazine analog compounds were more effective than the compounds from Table 1 of the '146 patent in 39 of the tests and less effective in only one. Furthermore, each of the 1,3,5-oxadiazine analog compounds had at least one insecticidal test in which the 1,3,5-oxadiazine proved more effective than the comparable 1,3,5-heterocycle of Table 1 of the '146 patent.²⁰ We find Maienfisch's evidence of unexpected results both credible and convincing.

Shiokawa contends that Maienfisch's alleged unexpected results are not commensurate in scope with Maienfisch's claims. According to Shiokawa, it is unrebutted that the 1,3,5-oxadiazine compounds S19 and S20, which fall within Maienfisch's claim 24, are not unexpectedly superior over their closest prior art. (Shiokawa Reply 4, Paper No. 95, p. 7). Shiokawa states that:

To overcome a showing of prima facie obviousness in instances where there are two or more "closest" prior art compounds, a test compound must show unexpected results over each of these "closest" prior art compounds. In re Johnson, 747 F.2d 1456, 1461, 223 USPQ 1260, 1264 (Fed. Cir. 1984). Since Maienfisch has clearly shown a lack of unexpected superior activity over all of the closest prior art throughout the entire claimed genus of compounds, it has not shown unexpected superior activity that is commensurate in scope with the scope of the claimed invention.

(Paper No. 95, p. 7).

²⁰As explained by Mr. Rindlisbacher:

Compounds that show no substantial activity in any of the tests are usually not tested further and are not considered candidates for development into insecticides. On the other hand, the fact that a compound shows little or no activity against a particular insect pest or a category of pests in this set of standard tests does not mean that the compound is not a viable candidate. Such a compound may still be a candidate if it shows good activity against other pests or categories of pests in other of these tests.

(Declaration of Alfred Rindlisbacher, MX 1034, p. 2).

Shiokawa fails to sufficiently explain why Maienfisch's testing of *eight* of the compounds specifically depicted in Table 1 of the '146 patent did not involve the "closest prior art." Specifically, the '146 patent does not appear to indicate that a particular specific subgenus or species would possess better or worse insecticidal properties than any other compound falling within the described genus of insecticidal heterocyclic compounds. Further, the '146 patent does not appear to indicate which of the forty compounds specifically depicted in Table 1 of the '146 patent will possess better or worse insecticidal properties than any other depicted compounds. Also, it does not appear that any of the compounds specifically compared to Maienfisch's S19 and S20 1,3,5-oxadiazines are explicitly mentioned in the '146 patent. (See MX 1034, Table 13 and Table 14 and note that E is N-CH₂CH₂ in Table 13 and N-CH₂CH₂CH₂ in Table 14). Moreover, Shiokawa has failed to sufficiently explain why one skilled in the art would be guided or directed to the analogs of S19 and S20 as representing the "closest prior art." In contrast, the eight compounds identified by Mr. Rindlisbacher in Table 19 of his declaration are specifically depicted in Table 1 of the '146 patent. (SX 2003, Table 1, Compounds numbered 11, 12, 14, 15, 16, 17, 19 and 23). It appears reasonable for one skilled in the art to select the eight compounds identified in Table 19 of Mr. Rindlisbacher's declaration as representative of the closest prior art for Maienfisch's claimed 1,3,5-oxadiazines.²¹

We find Maienfisch's evidence of unexpected results both credible and convincing. Maienfisch has sufficiently demonstrated that for the closest prior art the claimed 1,3,5-oxadiazine analogs generally provided, as a class, results that a person of ordinary skill in the art would have found

²¹As noted above, the examiner of Maienfisch's parent '931 application directed Maienfisch toward compound 23 of Shiokawa as representing the closest prior art.

surprising or unexpected. That two 1,3,5-oxadiazines, S19 and S20, were merely equivalent or in some instances less effective than compounds that do not appear to be specifically depicted or explicitly identified by the '146 patent does not alter our conclusion. Specifically, Maienfisch has provided convincing evidence that its claimed 1,3,5-oxadiazines would not have been obvious to one skilled in the art given the teachings of the JP '943 reference.

E. Shiokawa Preliminary Motion 13 to Suppress Maienfisch's Exhibit 1001

Shiokawa Preliminary Motion 13 requests that the Declaration of Dr. Fredrick E. Ziegler, Maienfisch Exhibit 1001, be suppressed. According to Shiokawa, the purpose of Dr. Ziegler's declaration was to support Maienfisch's arguments in its first and only preliminary motion. (Shiokawa Preliminary Motion 13, Paper No. 102, p. 15). Shiokawa alleges that Dr. Ziegler has demonstrated a level of skill in the relevant field of heterocyclic chemistry that falls below that of one of ordinary skill in the art.

In rendering our decision on preliminary motions, we have not found it necessary to rely upon the declaration testimony of Dr. Ziegler. Accordingly, the motion to suppress Dr. Ziegler's declaration testimony (MX 1001) is dismissed as *moot*.

F. Shiokawa Preliminary Motion 14 to Suppress Maienfisch's Exhibits 1005, 1006 and Paragraphs 48-49 of Exhibit 1001

Shiokawa Preliminary Motion 14 requests that Maienfisch Exhibits 1005 and 1006 and paragraphs 48 and 49 of Maienfisch Exhibit 1001, the Declaration of Dr. Fredrick E. Ziegler, be

suppressed. Paragraphs 48 and 49 of Dr. Ziegler's declaration, relate to the contents of Japanese Application No. 6-35254 filed on February 9, 1994. (Laid open no. 7-224062, MX 1006 and its translation MX 1005). According to Shiokawa, these exhibits are cited by Maienfisch as evidence of Shiokawa's lack of written description. Shiokawa, however, argues that MX 1005 and 1006 and the paragraphs 48 and 49 of MX 1001 are irrelevant because the issue of adequate written description is as of the filing date of the application relied upon and since the February 9, 1994 filing date is significantly after the alleged 1989 priority date of the involved Shiokawa '146 patent. Additionally, Shiokawa argues that these exhibits are irrelevant because the 1994 application merely states that the 1,3,5-oxadiazines are not "specifically" disclosed in the '146 patent.

As set forth in 37 CFR § 1.671(b), except as otherwise provided in the rule, the Federal Rules of Evidence shall apply to interference proceedings. As defined in the Federal Rules of Civil Procedure:

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

Fed. R. Evid. P. 401. Thus, the question of relevance is a question of whether the evidence tends to prove a disputed fact.

The JP '254 application is cited by Maienfisch as evidence that the '146 patent disclosure did not include a written description of the claimed 1,3,5-oxadiazines. (Maienfisch Opposition 14, Paper No. 112, p. 1). Maienfisch Exhibits 1005 and 1006 contain the statement that "The compounds of the present invention's application [1,3,5-oxadiazines and 1,3,5-triazines] can be conceptually included in the [JP '943] disclosure, but are not specifically disclosed therein." (MX 1005, p.3). As written

description - - a factual issue - - can be demonstrated through a patent specifications explicit disclosures, Maienfisch Exhibits 1005 and 1006 are relevant to the factual issue of the '146 patents lack of written description for the claimed 1,3,5-oxadiazines. Accordingly, Shiokawa's motion to suppress Maienfisch Exhibits 1005 and 1006 is *denied*. Furthermore, the suppression of paragraphs 48 and 49 of Dr. Ziegler's declaration is *moot* as we have not relied upon the declaration testimony of Dr. Ziegler.

III. Order

Upon consideration of the record, and for the reasons given, it is:

ORDERED that Shiokawa Corrected Preliminary Motion 1 is *denied*.

FURTHER ORDERED that Maienfisch Preliminary Motion 1 is *granted*.

FURTHER ORDERED that Shiokawa Preliminary Motion 4 is *denied*.

FURTHER ORDERED that Shiokawa Preliminary Motion 13 is *moot*.

FURTHER ORDERED that Shiokawa Preliminary Motion 14 is *moot* as to paragraphs 48 and 49 of the Declaration of Fredrick E. Ziegler, PhD and *denied* as to MX 1005 and 1006.

FURTHER ORDERED that judgment on priority as to Count 2, the sole count in interference, is awarded against Junior Party Shiokawa.

FURTHER ORDERED that Junior Party Shiokawa is not entitled to a patent containing claims 1-3 of Shiokawa, U.S. Patent No. 5,719,146. 35 U.S.C. § 102(g); 35 U.S.C. § 112 first paragraph (lack of written description).

FURTHER ORDERED that Senior Party Maienfisch is not entitled to a patent containing cancelled claims 26 and 27 of Maienfisch, U.S. Patent Application 09/136,664.

FURTHER ORDERED that a copy of this final decision shall be placed and given a paper number in the file of Shiokawa, U.S. Patent No. 5,719,146 and Maienfisch, U.S. Patent Application 09/136,664.

FURTHER ORDERED that if there is a settlement agreement, attention is directed to
35 U.S.C. § 135(c) and 37 CFR § 1.661.

FRED E. McKELVEY)	
Senior Administrative Patent Judge)	
)	
)	
)	
RICHARD TORCZON)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS
)	AND
)	INTERFERENCES
)	
)	
MICHAEL P. TIERNEY)	
Administrative Patent Judge)	

104,525
cc (via Federal Express):

Attorney for Shiokawa
(real party in interest Nihon Bayer Agrochem K.K.,
Bayer AG exclusive licensee):

Charles L. Gholz, Esq.
Alton D. Rollins, Esq.
OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.
1755 Jefferson Davis Highway
Arlington, VA 22202
Tel: 703-413-3000
Fax: 703-413-2220
E-mail: cgholz@oblon.com
E-mail: arollins@oblon.com

Robert J. Koch, Esq.
FULBRIGHT & JAWORSKI L.L.P.
801 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Fax: 202-662-4643

Attorney for Maienfisch
(real party in interest Novartis Corporation, a wholly
owned subsidiary of Novartis AG):

James Galbraith, Esq.
Thomas J. Meloro, Esq.
KENYON & KENYON
One Broadway
New York, NY 10004
Tel: 212-425-7200
Fax: 212-425-5288
E-mail: jgalbraith@kenyon.com
E-mail: tmeloro@kenyon.com

William A. Teoli, Jr., Esq.
NOVARTIS CORPORATION
564 Morris Avenue
Summit, NJ 07901-1027
Tel: 336-632-7706
Fax: 336-632-2012
E-mail: william.teoli@cp.novartis.com

TABLE OF CONTENTS

I.	Findings of Fact	2
A.	The Interference	2
B.	The Junior Party	2
C.	The Senior Party	2
D.	Disclosures of the Application and Patent Involved in the Interference	3
1.	Shiokawa’s ‘146 Patent	3
2.	Maienfisch’s ‘664 Application	11
E.	The Count	12
II.	Opinion	14
A.	Overview of Preliminary Motions	14
B.	Shiokawa Corrected Preliminary Motion 1 for Priority Benefit	16
1.	Case Law Analysis for According Priority Benefit	16
i.	<i>Fujikawa v. Wattanasin</i>	18
ii.	<i>In re Driscoll</i>	22
iii.	<i>In re Smith</i>	25
2.	Shiokawa’s Earlier Applications are not a Constructive Reduction to Practice of the Subject Matter of Count 1	27
i.	Shiokawa’s Claimed 1,3,5-Oxadiazine Subgenus is Narrower than Shiokawa’s Genus and Both Broader and Narrower than Shiokawa’s “Preferred” Subgenus	29
ii.	Shiokawa Makes Numerous Assumptions in Order to Demonstrate that the ‘146 Patent Guides One Skilled in the Art to the Claimed 1,3,5-Oxadiazines	30
iii.	Shiokawa’s Assumptions Evidence Obviousness Not Written Description	32

iv.	Many of Shiokawa’s Assumptions Regarding the Guidance Provided by the ‘146 Patent are Unsupported	35
v.	Example 5 of the ‘146 Patent does not Reasonably Convey that Shiokawa Invented Claimed 1,3,5-oxadiazines	38
vi.	Shiokawa Had Role in Creation of 1,3,5-Oxadiazine Claims . . .	41
vii.	Lack of Written Description Finding is Consistent with Statement Made by Several of the ‘146 Inventors	42
C.	Maienfisch Preliminary Motion 1 Alleging Lack of Written Description for Claims of ‘146 Patent	43
1.	Shiokawa Mischaracterizes the Decision in <i>Fujikawa</i>	43
2.	Dr. Zielger’s Testimony Does Not Establish Presence of 1,3,5-oxadiazine in Final Product of Example 5	44
3.	<i>In re Driscoll</i> is Readily Distinguish From the Facts of this Interference	45
4.	Maienfisch’s Published Abstract Does Not Evidence the Shiokawa’s Possession of the 1,3,5-oxadiazines	46
D.	Shiokawa Preliminary Motion 4 that Maienfisch’s Claims are Unpatentable over Prior Art	48
E.	Shiokawa Preliminary Motion 13 to Suppress Maienfisch’s Exhibit 1001	53
F.	Shiokawa Preliminary Motion 14 to Suppress Maienfisch’s Exhibits 1005, 1006 and Paragraphs 48-49 of Exhibit 1001	54
III.	Order	55