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UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Patent Interference 105,504 McK
Patent Interference 105,505 McK
Technology Center 1700

WAYNE L. **RYAN**,

Patent 6,723,563 B2,
Patent 6,653,137 B2,
Junior Party,

v.

CAROLE J. **YOUNG**, MICHAEL N. ELLIOTT,
NANCY R. NAYLOR-SCHLIPP and TIMOTHY J. FISCHER

Application 10/909,561,
Application 10/909,594,
Senior Party.

Before: FRED E. McKELVEY, *Senior Administrative Patent Judge*, and RICHARD TORCZON and SALLY GARDNER LANE, *Administrative Patent Judges*.

McKELVEY, *Senior Administrative Patent Judge*.

[AMENDED] DECISION ON MOTIONS

A. Statement of the case

The case is before a motions panel for entry of a decision on motions.

Oral argument was held on 19 September 2007. On 27 September 2007, an order was entered inviting the parties to submit additional briefing. Paper 100. On 29 October 2007, the parties timely responded to the invitation. Paper 104; Paper 106. Supplemental oral argument took place on 01 November 2007. We express our gratitude to counsel, and their respective clients, for responding to our invitation for additional briefing and for attending the supplemental oral argument.

References to a "Paper" followed by a number are references to entries in the file of Interference 105,504 unless otherwise noted.

Interference 105,504—Method of making control

Interference 105,504 was declared on 22 September 2006 (Paper 1).

The interference is between:

(1) Junior Party Wayne L. Ryan, based on U.S. Patent 6,723,563 B2, issued 20 April 2004 (**first Ryan patent**), based on application 10/005,999, filed 03 December 2001 (**first Ryan application**), and

(2) Senior Party (a) Carole J. Young, (b) Michael N. Elliott, (c) Nancy R. Naylor-Schlipp and (d) Timothy J. Fischer, based on application 10/909,561, filed 02 August 2004 (**first involved Young application**).

The real party in interest for Ryan is Streck Laboratories, Inc.

The real party in interest for Young is Beckman Coulter, Inc.

Count 1 is the only count:

A method according to (1) any of claims 1, 2, 11 or 20 of Ryan U.S. Patent 6,723,563 B2 or (2) any of claims 41, 50, 60, 69 or 86 of Young application 10/909,561.

Ryan claim 1

A method of making a control including a nucleated red blood cell component comprising the steps of:

a) providing a blood cell suitable for simulating a nucleated red blood cell, said blood cell including a membrane enclosing nucleus and cytoplasm, and wherein said blood cell is selected from the group consisting of reptile nucleated blood cells and fish nucleated blood cells;

b) stabilizing said membrane of said blood cell with said nucleus remaining therein to give a product; and

c) admixing the product of step b) in a suspension medium suitable for delivering said product of step b to a hematology analyzer for analysis.

Young claim 41

A method of making a control including a nucleated blood cell component comprising the steps of:

a) providing a blood cell suitable for simulating a nucleated blood cell, said blood cell including a membrane enclosing nucleus and cytoplasm;

b) removing cytoplasm from within said membrane, wherein said membrane is maintained around the remaining nucleus;

c) stabilizing said membrane with said nucleus remaining therein to give a product; and

d) admixing the product of step c) in a suspension medium suitable for delivering said product of step c to a hematology analyzer for analysis.

The claims of the parties are:

Ryan: 1-20
Young: 41-54, 60-73 and 86-87

The claims of the parties that correspond to Count 1 are:

Ryan: 1-20
Young: 41-54, 60-73 and 86-87

The claims of the parties that do not correspond to Count 1 are:

Ryan: None
Young: None

The parties have been accorded the following earlier constructive reductions to practice (*i.e.*, benefit for the purpose priority) for Count 1:

Ryan: None

Young: Application 10/214,717, filed 09 August 2002

Application 08/787,408, filed 22 January 1997, now U.S. Patent 6,509,192, issued 21 January 2003.

Application 08/432,435, filed 28 April 1995.

Young is Senior Party based on its accorded priority date of 28 April 1995, which is over five years prior to Ryan's earliest date which is 03 December 2001.

Interference 105,505—Method using a control

Interference 105,505 was declared on 22 September 2006 (Int. 105,505, Paper 1).

The interference is between:

(1) Junior Party Wayne L. Ryan, based on U.S. Patent 6,653,137 B2, issued 25 November 2003 [**second Ryan patent**], based on application 10/007,519, filed 03 December 2001 [**second Ryan application**], and

(2) Senior Party (a) Carole J. Young, (b) Michael N. Elliott, (c) Nancy R. Naylor-Schlipp and (d) Timothy J. Fischer, based on application 10/909,594, filed 02 August 2004 [**second involved Young application**].

The real party in interest for Ryan is Streck Laboratories, Inc.

The real party in interest for Young is Beckman Coulter, Inc.

Interference 105,505 has been consolidated with Interference 105,504 (Paper 20).

Initially, Interference 105,505 was declared with Count 1 (Int. 105,505, page 7).

Young Substantive Motion 2 (Paper 33) has been granted (Paper 38). As a result, Young claims 40, 42, 45, 58, 61, 65 and 68 containing improper Markush language "selected from the group comprising" were cancelled and

Young claims 69-75 containing correct Markush language "selected from the group consisting of" were added.

As a result of the motion being granted, the interference was redeclared (Paper 39) to substitute original Count 1 with current Count 2.

Count 2 is the only count (Paper 39):

> A method according to (1) any of claims 1, 5, 9 or 13 of Ryan U.S. patent 6,653,137 B2 or (2) any of claims 43, 49, 51, 54, 59-60, 62-64, 67, 69 or 72-75 of Young application 10/909,594.

The claims of the parties are:

Ryan:	1-14
Young:	43, 49, 51, 54, 59-60, 62-64, 67 and 69-75

The claims of the parties which are designated as corresponding to Count 2 are:

Ryan:	1-14
Young:	43, 49, 51, 54, 59-60, 62-64, 67 and 69-75

The claims of the parties which are designated as not corresponding to Count 2 are:

Ryan:	None
Young:	None

Ryan claim 1
as corrected by a Certificate of Correction
issued 14 September 2004

> A method of using a control including a nucleated red blood cell component comprising the steps of:
>
> a) providing a control including a stabilized blood cell suitable for simulating a nucleated red blood cell, the stabilized blood cell including a membrane enclosing a nucleus and

wherein the cytoplasm of the stabilized blood cell has been substantially removed from within said membrane;

b) providing a hematology analyzer for analyzing a blood cell sample by at least to angles of light scatter measurement to differentiate nucleated red blood cells from other cell types;

c) passing the control through the hematology analyzer for detection of the simulated nucleated red blood cells; and

d) reporting nucleated red blood cells in said control.

Young claim 69 [replacing Young claim 40]

A method of using a hematology control product including at least one nucleated blood cell analog comprising the steps of:

a) providing a hematology control product including a nucleated blood cell analog, wherein the analog is a blood cell including a membrane enclosing a nucleus and hemoglobin, wherein the blood cell has been treated so that said membrane is resistant to degradation, and wherein 20% to 80% by weight of the hemoglobin in the blood cell has been removed;

b) providing an instrument for analyzing a blood cell sample by at least two physical properties selected from the group consisting of DC volume, RF size, opacity, and light scatter;

c) passing the control product through the instrument for detection of said nucleated blood cell analog; and

d) reporting said nucleated blood cell analog in the control product.

The parties have been accorded the following earlier constructive reductions to practice (*i.e.*, benefit for the purpose of priority) for Count 2:

Ryan: None

Young: Application 10/214,717, filed 09 August 2002

Application 08/787,408, filed 22 January 1997, now U.S. Patent 6,509,192, issued 21 January 2003.

Application 08/432,435, filed 28 April 1995.

Young is Senior Party based on its accorded priority date of 28 April 1995, which is over five years prior to Ryan's earliest date which is 03 December 2001.

Motions

Substantive, responsive and miscellaneous motions have been presented for our consideration.

Ryan Motion 1

Ryan Motion 1 (Paper 32) seeks entry of a judgment against Young based on an alleged failure of Young to comply with the written description and enablement requirements of 35 U.S.C. § 112. Young timely opposed (Paper 56). Ryan timely replied (Paper 69).

Ryan Motion 2

Ryan Motion 2 (Paper 35) seeks entry of judgment against Young based on an alleged failure of Young to comply with the provisions of

35 U.S.C. § 135(b)(2). Young timely opposed (Paper 57). Ryan timely replied (Paper 70).

Ryan Miscellaneous Motion 4

Ryan Miscellaneous Motion 4 (Paper 81) seeks to exclude from evidence Exhibits:

1033,
1036,
1039,
1051,
1073 and
1093

all filed by Young. Young timely opposed (Paper 89). Ryan timely replied (Paper 91).

Young Motion 1

Young Motion 1 (Paper 53) seeks entry of a judgment against Ryan based on alleged unpatentability under 35 U.S.C. § 103 over the prior art. Ryan timely opposed (Paper 58). Young timely replied (Paper 67).

Young Responsive Motion 3

Young Responsive Motion 3 (Paper 36) is a responsive motion to Ryan Motion 1. Proposed Young claim 88 would be added to involved Young application 10/909,561. Proposed Young claim 76 would be added to involved Young application 10/909,594. Ryan timely opposed (Paper 59), maintaining that the motion should not be granted because proposed claims 88 and 76 do not comply with (1) the written description and enablement requirements of 35 U.S.C. § 112 and (2) the provisions of 35 U.S.C. § 135(b)(2). Young timely replied (Paper 68).

Young Miscellaneous Motion 4

Young Miscellaneous Motion 4 (Paper 77) seeks entry of an order striking Ryan reply 1 (Paper 69). According to Young, the reply for the first time attacks Young's claims as being unpatentable under 35 U.S.C. § 102(b). Ryan timely opposed (Paper 79). Young timely replied (Paper 84).

Young Miscellaneous Motion 5

Young Miscellaneous Motion 5 (Paper 85) seeks to exclude from evidence Exhibits:

2060 (¶¶62-63),
2063,
2070 through 2077,
2083,
2107 (¶¶ 4-5, 24-30, 38-40), and
2109

all filed by Ryan. Ryan timely opposed (Paper 88). Young timely replied (Paper 90).

B. Interference motion practice

At oral argument, counsel for both parties in arguing one motion made reference to the record in another motion.

We take this opportunity to discuss two important facets of motions practice before the Board in interference cases.

(1)

All evidence in an interference is presented to the Board in the form of an exhibit.

When is an exhibit "in evidence" before the Board?

A *first* condition for an exhibit to be considered "in evidence" before the board is that the exhibit must be filed. All exhibits are normally filed in

the motions phase at Time Period 8 and in the priority phase at Time Period 18. On relatively rare occasions, the Board may require an exhibit to be filed earlier.

During an interference, a party may use an exhibit (*e.g.*, in a cross-examination deposition of an opponent's witness) and ultimately decide not to rely on the exhibit. Under this circumstance, the exhibit is neither filed nor discussed in an opposition. The exhibit would not be in evidence. Nevertheless, the opponent could list and rely on the exhibit in a reply, in which case the exhibit would be submitted by opponent when exhibits are filed...

A *second* condition is that the exhibit must be listed and discussed in a motion, opposition or reply.

If a miscellaneous motion to exclude an exhibit is granted, the exhibit is not in evidence and will not be considered.

Moreover, an exhibit is considered "in evidence" only to the extent that the exhibit or a portion of the exhibit is mentioned and relied upon in a motion, opposition or reply. A party cannot list and rely on an exhibit for one purpose in the motions and sometime later in the proceeding, *e.g.*, during the priority phase, rely on the exhibit for another purpose unless the motion is again listed and relied upon for the other purpose in a motion for judgment based on priority.

(2)

A procedural requirement for properly filing a motion, opposition or reply is that the motion, opposition or reply list the evidence relied upon in the motion, opposition or reply.

Each motion is considered on its own merits solely on the basis of the evidence relied upon in support of the motion, opposition or reply.

An exhibit listed and relied upon in a first motion, *e.g.*, motion 1, cannot be relied upon in a second motion, *e.g.*, motion 2, unless the exhibit is also listed and discussed in motion 2.

Admission of evidence before the Board differs from trial practice in Federal Court where generally once an exhibit is admitted in evidence, the exhibit can be relied upon in support of or in opposition to any issue.

In an interference with multiple motions, each motion should be viewed as a separate proceeding independent of other motions at least for the purpose of determining what evidence will be considered in resolving a given motion.

Board practice allows the Board to allocate resources by assigning one panel judge to one motion and another panel judge to another motion. *Cf.* Interference 105,402 where an opinion resolving one set of motions was authored by one judge (Int. 105,402, Paper 114) and an opinion resolving a different set of motions was authored by another judge (Int. 105,402, Paper 115). *Cf. Joy Technologies, Inc. v. Quigg*, 12 USPQ2d 1112 (D.D.C. 1989) (Judge Gasch decided question of whether jury trial available in civil action under 35 U.S.C. § 145) and *Joy Technologies, Inc. v. Manbeck*, 17 USPQ2d 1257 (D.D.C. 1990) (Judge Bennett decided patentability on the merits).

Another administrative advantage of Board practice is that it minimizes the chance that an opponent will be surprised or blindsided or that the Board will inadvertently consider an exhibit listed in one motion when

deciding another motion—reliance on evidence not relied upon by a party can be prejudicial to an opponent.

C. Background of technology

Blood cells

Blood is a suspension of small, highly concentrated cells in plasma. Paper 32, page 3; Ex 2003, ¶ 9.

Blood includes white blood cells and red blood cells.

Red blood cells are known as "erythrocytes."

White blood cells are known as "leukocytes."

Red blood cells are smaller than white blood cells, but red blood cells outnumber white blood cells in the neighborhood of 1000 red blood cells for each white blood cell.

For the most part, human and other mammal red blood cells do not have a nucleus, but are rich in hemoglobin. Ex 2003, ¶ 10.

However, human red blood cells from umbilical cords can be nucleated. Ex 2003, ¶ 11; Ex 2048, ¶ 2; Ex 2006, (nucleated red blood cell shown in blue).

The presence of nucleated red blood cells in adult human blood indicates "a serious medical concern." Ex 2003, ¶ 11. Paper 108 [transcript of first oral argument], page 5:25 through page 6:4.

Some non-mammal animals have red blood cells with a nucleus and the cells can be larger than human red cells. Ex 2003, ¶ 12.

The non-mammal animals include fish, amphibians, reptiles and birds, whose red blood cells are larger than mammalian red blood cells. Ex 2003, ¶ 12; Ex 2007.

White blood cells contain a nucleus and cytoplasm, but no hemoglobin. Ex 2003, ¶ 13.

Hematology

Hematology is the study of the nature, function and diseases of the blood. Ex 2003, ¶ 14.

Instruments used to analyze blood are known as hematology analyzers. Ex 2003, ¶ 14.

One function of a hematology analyzer is to count the various blood cells, *i.e.*, how many red cells and how many white cells are present in a given sample of blood.

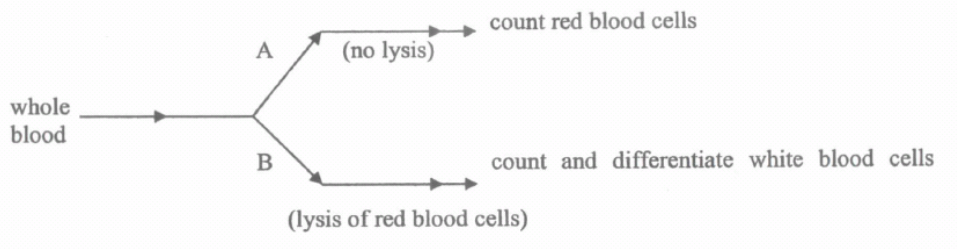
To confirm the accuracy of measurements, it is necessary to have quality control materials that simulate a blood specimen.

The controls may contain stabilized cells which serve as "analogs" for various blood cells and are designed to simulate the measured characteristics of blood components being analyzed.

In effect, a control is used in an analyzer to calibrate the analyzer and ensure that the analyzer is working properly.

A control may have more than one analog.

Ryan provides the following "simplified flow diagram" of a hematology analysis:



Whole blood (meaning a blood sample from a patient undergoing examination) is delivered to a hematology analyzer.

The sample is split into parallel channels A and B.

In channel A, whole blood is analyzed in order to count the red blood cells.

The presence of white cells in channel A generally does not impact the enumeration of red blood cells because any white cells are greatly outnumbered by red blood cells.

While there may be some disagreement on whether lysing of red blood cells is necessary (*see, e.g.*, Ex 2003, ¶ 46 versus Ex 1041, ¶ 100), it appears generally that whole blood in channel B is treated with a lysing agent in order to "burst" the red blood cells (*i.e.*, destroy the red cell structure) so that any red cells do not interference with the enumeration of white blood cells. White blood cells can then be counted.

D. Level of skill in the art

The parties presented evidence on the level of skill in the art.

Ryan witness Dr. Warren Groner (*see, e.g.*, Ex 2003) and Young witness Dr. James L. Wyatt (*see, e.g.*, Ex 1041) testified on the level of skill in the art.

Dr. Wyatt testified on direct about the level of skill in the art (*see, e.g.*, Ex 1041, page 32, ¶ 222 through page 37, ¶ 260).

Dr. Groner has also testified, mostly on cross-examination (*see, e.g.*, Ex 1040, page 15:1 through page 16:17), about the level of skill in the art.

In resolving any factual issue concerning the level of skill in the art, we do, and need not, decide whether Dr. Wyatt or Dr. Groner is a person

having ordinarily skill in the art. Rather, we look to see what both tell us about what the hypothetical person of skill in the art would know.

According to Dr. Wyatt, the level of skill at the relevant time was "high."

While a "high" skill level *per se* does not tell us much, what Dr. Wyatt means by "high" is that a person of ordinary skill in the art of designing and developing hematology controls would have an advanced degree, meaning either a Masters degree or a Ph.D is a bioscience. Ex 1041, ¶¶ 222-224. *See also* Ex 1040, page 15:17:24 and page 111:23 through 112:4.

Educational degrees in and of themselves often do not tell us much. *Argyropoulos v. Swarup*, 56 USPQ2d 1795, 1807 (Bd. Pat. App. & Int. 2000) (explaining why defining the level of skill in the art in terms of degrees obtained is less helpful than defining it in terms of what such a person would have known and what the person would have been able to do).

However, Dr. Wyatt follows up with why having an advanced degree (*i.e.*, a degree beyond a Bachelor's degree) is significant.

A person with a Masters degree has completed some type of laboratory project that a person with a Bachelor's degree has not. Ex 1041, ¶ 225.

The person with an advanced degree would (1) have a broader perspective of the cell properties that are subject to manipulation and analysis and (2) be more knowledgeable about the nuances of cell manipulation techniques. Ex 1041, ¶ 226.

A person having ordinary skill in this art would have had experience in development of controls for use in commercial analyzers. Ex 1041, ¶ 230. *See also* Ex 1040, page 16:7-11.

The person would have had experience in cell handling and in cell biology, as well as an understanding of biology in general. Ex 1041, ¶ 229.

The person would not have been a mere technician following the instructions of others for making and using controls. Ex 1041, ¶ 232. In other words, to quote *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1742 (2007), the person would not be an "automaton".

The person would have had experience in testing controls in hematology analyzers. Ex 1041, ¶ 233. *See also* Ex 1040, page 16:12-17 (Dr. Groner agreed the person would have had experience directed to designing and preparing commercial controlled preparations for blood analyzers).

Significantly, in Dr. Wyatt's opinion, the person following a known method of making a control, would be expected to run it through a hematology analyzer to see what results are obtained and to make any adjustments necessary to the method. Ex 1041, ¶ 235.

The person would have an understanding of the biology of any sources cells, including which have nuclei and which do not, and of techniques for adjusting cells. Ex 1041, ¶ 239.

The person would have been able to direct or conduct the process of manipulating by laboratory processes the properties of a source cell so that it mimicked a target cell to provide the same response in a given analyzer. Ex 1041, ¶ 240.

The person would understand that a hematology analyzer would be used to analyze whole blood, including white cells, platelets and red cells. Ex 1041, ¶ 246.

The person would be aware of the different types of signals used in analyzers, how those signals indicate the presence of various types of cells, and would understand that analyzers could detect a target blood cell using one or more tools, such as DC volume, RF impedance and light scatter at various angles of measurement. Ex 1041, ¶¶ 247-248.

Dr. Wyatt goes on to state other qualifications the person of ordinary skill would possess. Ex 1041, ¶¶ 249-260.

Our impression is that a person of ordinary skill in the art, in addition to what the prior art in the case reveals, knows quite a bit about blood, testing blood samples, using analyzers and making controls.

E. Ryan Motion 2

Pursuant to 37 C.F.R. § 41.125(a) (2007), we exercise discretion to consider first Ryan Motion 2. *See also Berman v. Housey*, 291 F.3d 1345, 1351 (Fed. Cir. 2002).

Ryan Motion 2 seeks judgment against Young based on Young's alleged failure to comply with 35 U.S.C. § 135(b) (2).

Findings of fact

Ryan applications and patents

Involved Ryan patent 6,723,563 B2 issued 20 April 2004 (**first Ryan patent**) based on application 10/005,999 filed 03 December 2001 (**first Ryan application**). Ex 1001.

The first Ryan application was published as U.S. Patent Application Publication 2003/0104630 A1 on 05 June 2003. Ex 2017.

Involved Ryan patent 6,653,137 B2 issued 25 November 2003 (**second Ryan patent**) based on application 10/007,519, filed 03 December 2001 (**second Ryan application**). Ex 1002.

The second Ryan application was published as U.S. Patent Application Publication 2003/0104629 A1 on 05 June 2003. Ex 2016.

Young applications

Young filed Young application 10/214,717 on 09 August 2002 (**first Young application**). Ex 1069, page 1.

On 08 October 2004, Young filed an amendment ("**Supplemental Amendment**") in which numerous "new" claims were presented. Ex 1069.

One of those new claims was Young claim 81 (Ex 1069, page 21):

> A method of making a control including a nucleated blood cell component comprising the steps of:
>
> a) providing a blood cell suitable for simulating a nucleated blood cell, said blood cell including a membrane enclosing nucleus and cytoplasm;
>
> b) removing cytoplasm from within said membrane, wherein said membrane is maintained around the remaining nucleus;
>
> c) stabilizing said membrane with said nucleus remaining therein to give a product; and

d) admixing the product of step c) in a suspension medium suitable for delivering said product of step c to a hematology analyzer for analysis.

As is apparent, Young claim 81 presented in the first Young application is the same as involved Young claim 41.

The Examiner (1) determined that certain Young claims (including Young claim 81) were directed to an invention which was independent and distinct (35 U.S.C. § 121) from the invention then being claimed by Young and (2) required restriction. Ex 1072, page 2, ¶ 1 (a restriction requirement was entered on 28 December 2004; this fact is not apparent from Ex 1072, but we take official notice based on PTO records that the restriction was entered on 28 December 2004).

As a result of the Examiner's requirement for restriction, Young elected to prosecute the invention of claim 81 in involved Young application 10/909,561, which previously had been filed on 02 August 2004. Ex 1003.

Involved Young application 10/909,561 is characterized as a "continuation" of the first Young application. Ex 1003, page 1.

Involved Young claim 41 was presented in the involved Young application as filed.

As noted earlier, Young filed the first Young application on 09 August 2002. Ex 1069, page 1.

On 08 October 2004, Young filed an amendment ("Supplemental Amendment") in which numerous "new" claims were presented. Ex 1069.

One of those new claims was Young claim 52 (Ex 1069, pages 9-10) [italics added]:

> A method of using a hematology control product including at least one nucleated blood cell analog comprising the steps of:
>
> a) providing a hematology control product including a nucleated blood cell analog, wherein the analog is a blood cell including a membrane enclosing a nucleus and hemoglobin, wherein the blood cell has been treated so that said membrane is resistant to degradation, and wherein 20% to 80% by weight of the hemoglobin in the blood cell has been removed;
>
> b) providing an instrument for analyzing a blood cell sample by at least two physical properties selected from the group *comprising* DC volume, RF size, opacity, and light scatter;
>
> c) passing the control product through the instrument for detection of said nucleated blood cell analog; and
>
> d) reporting said nucleated blood cell analog in the control product.

Young claim 52 presented in the first Young application is the same as involved Young claim 69 with one exception: "consisting of" has replaced "comprising" by virtue of the granting of Young miscellaneous motion 2. The difference is not a substantive difference; rather, it merely corrects improper Markush language.

The Examiner (1) determined that certain Young claims (including claim 52) were directed to an invention which was independent and distinct

(35 U.S.C. § 121) from the invention then being claimed in the first Young application and (2) required restriction. Ex 1072, page 2, ¶ 1.

As a result of the Examiner's requirement for restriction, Young elected to prosecute the invention of claim 52 in the involved Young application 10/909,594, which previously had been filed on 02 August 2004. Ex 1004.

Involved Young application 10/909,594 is characterized as a "continuation" of the first Young application. Ex 1003, page 1.

What was Young claim 52 in the first Young application became Young claim 40 of the involved Young application, as filed.

As noted earlier, Young claim 40 has been cancelled and has been replaced with Young claim 69.

A chronological summary of events follows:

1.	12-03-2001	First Ryan application filed
	12-03-2001	Second Ryan application filed
2.	08-09-2002	First Young application 10/214,717 filed
3.	06-05-2003	First Ryan application published
	06-05-2003	Second Ryan application published
4.	11-25-2003	Second Ryan patent issued
5.	04-20-2004	First Ryan patent issued
6.	08-02-2004	Involved Young application 10/909,561 filed
	08-02-2004	Involved Young application 10/909,594 filed
7.	10-08-2004	Claims presented in first Young application
8.	12-28-2004	Restriction required in first Young application

Young maintains that 35 U.S.C. § 135(b) (2) does not apply, because the first Young application was filed before the first and second Ryan applications were published.

Ryan maintains that 35 U.S.C. § 135(b) (2) applies, because the claims in the first Young application were presented more than one year after the first and second Ryan application were published.

Section 135(b) (1) does not apply to this case, because the claims in the involved Young applications were presented less than a year after the first and second Ryan patents issued.

Analysis

Section 135(b) (2) reads:

> A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an application published under section 122(b) of this title may be made in an application filed after the application is published only if the claim is made before 1 year after the date on the application is published.

Young maintains that it should prevail for three reasons.

First, by virtue of 35 U.S.C. § 120, the involved Young claims are entitled to the benefit of an earlier filing date, *viz.*, 09 August 2002 which is a date prior to the publication of the Ryan applications.

Second, the involved Young claims were presented in an application filed prior to the publication of the Ryan applications.

Third, Ryan has failed to establish that the subject matter of the claims in its published Ryan applications is not materially different from the subject matter of the claims in the Ryan patents.

Young prevails if it is right on any one of its reasons. Ryan can prevail only if Young is wrong on all three reasons. In our view, Young is wrong in all respects regarding Interference 105,504 involving a method for making a control. On the other hand in Interference 105,505, we agree with Young that the claims of the second Ryan patent (6,653,137 B2) contain material limitations vis-à-vis the claims published in second published Ryan application (2003/0104629 A1).

Reason (1)

A.

Ryan maintains that the statutory language "in an application filed after" precludes applying the provisions of 35 U.S.C. § 120 to that application for the purpose of evaluating compliance with 35 U.S.C. § 135(b) (2). We disagree. *See Ding v. Singer*, Interference 105,436, Paper 36, pages 8-13) (Bd. Pat. App. & Int. 2007) (available at https://acts.uspto.gov/ifiling/PublicView.jsp?identifier=105436&identifier2=null&tabSel=4&action=filecontent&replyTo=PublicView.jsp followed by inserting the interference number, clicking on file contents and clicking on Document 56).

The first sentence of § 120 states in relevant part:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 … in an application previously filed in the United States … shall have the same effect, as to such invention, as though filed on the date of the prior application ….

The portions of § 120 dealing with same inventors and copendency have not been quoted. The Young inventors are the same and there has been no suggestion of a lack of copendency.

The starting point for interpreting a statute is the language of the statute. *United States v. Goodyear Tire and Rubber Co.*, 493 U.S. 132, 138 (1969); *Kelly v. Robinson*, 479 U.S. 36, 43(1986). Words in a statute will be interpreted as having their ordinary, contemporary and common meanings. *Perrin v. United States*, 444 U.S. 37, 42 (1979). Statutes relating to the

same thing ought to be taken into consideration in construing any one of them, and it is a rule of law that all statutes *in pari materia* are to be taken together, as if they were one law. *United States v. Freeman*, 3 How. (44 U.S.) 556, 564 (1845). A reading of a statute that would lead to absurd results is to be avoided when it can be given a reasonable application consistent with its words. *Haggar Co. v. Helvering*, 308 U.S. 389, 394 (1940).

The *in pari materia* statutory construction canon trumps Ryan's argument. Both § 120 and § 135(b)(2) use the word "application" and there is no reason to believe that Congress intended to have "application" mean one thing in § 135(b)(2) and something else in § 120 and thereby exclude the earlier filing date benefits of § 120 to applications filed after an application is published.

Nor would it make sense to restrict the applicability of § 120 in cases involving § 135(b) (2). The facts of this case show why. Congress authorized applicants to file applications. Congress further authorized the Director to restrict applications to a single independent and distinct invention. 35 U.S.C. § 121. Congress still further authorized the filing of a different application to permit applicants to prosecute the invention restricted out of their earlier application. 35 U.S.C. §§ 120, 121. Here the Examiner made a restriction requirement in a Young application filed before the Ryan applications were published. Although Young filed the involved Young applications before the restriction requirement was made, Young nevertheless had a right to take advantage of a congressional authorization to

file its continuing applications to pursue that which the Examiner would not allow to be pursued in the first Young application.

Ryan says, in effect: "Too bad--the statute says nothing about § 120 and so it is not available." However, § 120 applies on its face. We will not impute to Congress an intent to exclude the application of § 120 without some clear legislative history.

Under Ryan's construction of § 135(b)(2), an applicant could exercise a § 120 right to antedate § 102(b) prior art, but could not exercise a similar opportunity to antedate a § 135(b)(2) bar based on an application filed before publication where the vary claims in issue were presented.

Ryan makes reference to 35 U.S.C. § 154(a) (2) relating to patent terms. Congress determined that if an applicant relies under § 120 on an earlier application date, patent term is 20 years from the filing of the earlier application and not the application which matured into a patent. The reference to § 120 was necessary in § 154(a) (2) in order to accomplish a congressional objective of eliminating "submarine" patents. No such reference is necessary in § 135(b) (2). The language of § 120 permits an applicant to rely on its provisions for all purposes during examination of a patent application, including establishing an earlier date for avoiding both § 102(b) bars and § 135(b) (2) bars.

B.

1.

To successfully claim benefit under 35 U.S.C. § 120, the involved Young claims must be described in the first Young application in the manner required by the first paragraph 35 U.S.C. § 112. As will become apparent

later in this opinion, we believe that the subject matter described in the first Young application, in combination with the prior art, would have rendered obvious the subject matter which Young now claims in the involved Young applications. But, "obviousness" is not the test for complying with the written description requirement. *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1567-68 (Fed. Cir. 1997) ("Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention."); *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) ("The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.").

Federal Circuit precedent also tells us that when relying on an earlier claim for the purpose of § 135(b)(1), the claim which was "timely" presented must find support. *University of California v. University of Iowa Research Foundation*, 455 F.3d 1371, 1376-77 (Fed. Cir. 2006). The same result seemingly is appropriate under § 135(b)(2).

2.

Ryan maintains that the subject matter of the involved Young claims is not described in the first Young application. Ryan acknowledges that the first Young application contains extensive discussion of nucleated white blood cells. Ryan maintains that there is no description of nucleated red blood cells. Ryan reasons that Young does not describe a generic invention

dealing with nucleated blood cells. Ryan offers the testimony of Dr. Warren Groner in support of its position. Ex 2003 (direct); Ex 1040 (cross-examination).

Young maintains that the first Young application contains a written description of a method for making and using nucleated blood cells generally (which would include nucleated red blood cells). Young has to acknowledge, however, that the first Young application does not mention *explicitly* a method for making or using a control analog of "nucleated blood cells" generally or "nucleated red blood cells" in particular. Young maintains, however, that the disclosure in the first Young application has sufficient information to *enable* one skilled in the art to make and use control analogs of "nucleated blood cells," including "nucleated red blood cells." Young offers the testimony of Dr. James L. Wyatt in support of its position. Ex 1041 (direct). Dr. Wyatt was not cross-examined.

3.

Dr. Groner and Dr. Wyatt have impressive credentials. Both appear to be well-versed in the relevant art before us. While they agree on some points, they disagree on other points. In making our credibility assessment in this case we have considered not only the portions of the testimony cited throughout this opinion, but the testimony as a whole, including relevant cross-examination. As will become apparent, we find that Dr. Groner focuses on *description* (a finding of fact) in the first Young application in a way we find highly credible. Dr. Wyatt, on the other hand, focuses on *enablement* (a legal issue) of the involved Young applications in a way which we find highly credible.

In this case, the description issue is the controlling issue on the question of benefit under 35 U.S.C. § 120. For these reasons, as well as an overall assessment of the respective testimony of both witnesses, and to the extent there is a conflict between the testimony of Dr. Groner and that of Dr. Wyatt *on the issue of written description of the first and second Young applications*, we credit the testimony of Dr. Groner over that of Dr. Wyatt. On the other hand, *on the issue of enablement of the involved Young applications* (discussed in Part F), we credit the testimony of Dr. Wyatt over than of Dr. Groner.

4.

One significant fact is that, as filed, the first Young application did not have an original claim to a "nucleated blood cell." Because the original claims in the involved Young application claimed a "nucleated blood cell" and since original claims form part of the disclosure of an application, it becomes apparent that the original disclosure of the first Young application is not exactly the same as the original disclosure of the involved Young application.

The difference alone, however, does not mean that "nucleated blood cells" are not described in the first Young application. Rather, we determine whether "nucleated blood cells" are described in the first Young application based on the actual description in the first Young application (the best evidence of what is described therein) and the testimony by Dr. Groner and Dr. Wyatt as to what one skilled in the art would have understood from the first Young application.

The governing principles are set out in *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996) (**(1)** 1171: The issue of whether a patent specification adequately describes the subject matter claimed in a question of fact; **(2)** 1172: The adequate written description requirement, which is distinct from the enablement and best mode requirements, serves 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 him; how the specification accomplishes this is not material. In order to meet the adequate written description requirement, the applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed, but the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. The applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Precisely how close the original description must come to comply with the description requirement of section 112 must be determined on a case-by-case basis. **(3)** 1174: Evidence addressing written description factual issue is properly considered.) .

5.

Dr. Groner acknowledges that the term "nucleated blood cell" is generic to white blood cells (which contain a nucleus) and nucleated red blood cells. Ex 2003, pages 8-9, ¶ 20.

The first Young applications, however, never mention a method for making or using a control analog for nucleated red blood cell. Ex 2003, page 8, ¶ 21.

Nor beyond discussing white blood cells, does the first Young application mention a method for making or using a control analog for nucleated blood cells. Ex 2003, page 8, ¶ 22.

The first Young application focuses on making analogs for named white blood cells. Ex 2003, page 8, ¶ 23.

We agree with Dr. Groner, and therefore find, that the first Young application would not have reasonably conveyed, to one skilled in the relevant art of hematology analyzers and controls, that Young had invented a method of making or using an analog for a generic class of "nucleated blood cell's or a method of making or using an analog for a nucleated red blood cell. Ex 2003, page 8, ¶ 24.

Dr. Groner takes us through the first Young application, pointing out precisely what can be found in the application.

Starting with the summary of the invention (Ex 1003, numbered page 12—note that the first two pages of Ex 1003 are not page numbered), Dr. Groner notes, and we agree, that summary discusses a method for making and using an analog for a white blood cell. Ex 2003, pages 8-10, ¶ 25.

No nucleated red blood cell is mentioned in the summary.

No reference to nucleated blood cells is mentioned in the summary.

A (1) leukocyte analog (Ex 1003, page 13:1), (2) leukocyte analog population (Ex 1003, page 13:15-16), and (3) leukocyte subpopulation (Ex 1003, page 14:4-5) are mentioned. All involve white blood cells.

Dr. Groner discusses the detailed description of the invention section of the first Young application (Ex 1003, pages 14-69).

No method for making or using a nucleated red blood cell analog is mentioned in the detailed description of the invention.

What is mentioned, as Dr. Groner correctly points out, are multiple references to analogs for white blood cells, some of which are made from non-human nucleated red blood cells. Ex 2003, page 10-11, ¶ 26.

One reference is to current multiple white blood cell population analysis. Ex 1003, page 20:20.

Another reference is what Dr. Groner refers to as a general method for making leukocyte analogs. Ex 1003, page 21:21 and Ex 2003, page 11:2-16.

The first Young application teaches that the process also enables the swelling of red blood cells greater than 50% of their original volume which is said to provide a wider latitude in the selection of animal cells for producing the desired analogs—which we note are white blood cells analogs. Ex 1003, page 22:7-12.

The first Young application also teaches that the cells of birds, alligators and nurse sharks are nucleated, but the presence of a nucleus is neither essential nor detrimental for their use as a substitute for human white blood cells, given the process described in the application which is said to permit a regulated hemolysis of the red blood cell. Ex 1003, page 23:3-8.

Dr. Groner discusses Young's "preferred process" which embodies a composition prepared by mixing a suspension of fixed goose red blood cells to simulate human lymphocytes (white blood cells) or fixed alligator red blood cells to simulate human monocytes, neutrophils, and eosinophils (all white blood cells). Ex 2003, pages 11-12; Ex 1003, page 23:24-31.

As recognized by Dr. Groner, the first Young application contains six examples. Ex 2003, page 12, ¶ 29.

Example 1 (Ex 1003, page 55) describes a method for preparing an analog for a lymphocyte (which Dr. Groner characterizes as a white blood cell subpopulation) involving the step of treating goose red blood cells to make an analog that is said to simulate human lymphocyte cells in normal human blood. Ex 2003, page 13, ¶ 30.

Example 2 (Ex 1003, page 58) describes a method for preparing an analog for a monocyte (which Dr. Groner characterizes as another white blood cell subpopulation) involving treating alligator red cells to make an analog that is said to simulate human monocyte cells in normal human blood. Ex 2003, pages 13-14, ¶ 31.

Example 3 (Ex 1003, page 60) describes a method for making an analog for eosinophil (which Dr. Groner characterizes as another white blood cell subpopulation) involving treating alligator red blood cells to make an analog that simulates human eosinophil cells in normal human blood. Ex 2003, page 14, ¶ 32.

Example 4 (Ex 1003, page 62) describes a method for making an analog for neutrophil (which Dr. Groner characterizes as another white blood cell subpopulation) involving treating an alligator red blood cell to make an analog that simulates a human neutrophil cell in normal human blood. Ex 2003, page 14, ¶ 33.

Example 5 (Ex 1003, page 64) describes "fixing" white blood cells from human blood to simulate human leukocyte cells in normal human blood. Ex 2003, page 14, ¶ 34.

Example 6 (Ex 1003, page 66) describes a sub-assembly for simulating white blood cells in normal human blood; the sub-assembly is made by combining the analogs prepared by Examples 1-4 with various components to simulate human blood. Ex 2003, page 15, ¶ 35.

Based on the specification of the first Young application, as a whole, we agree with Dr. Groner that one skilled in the art reading the first Young application would have come to the conclusion that Young's invention was directed solely to methods for making and using a control containing an analog for a white blood cell or white blood cell subpopulations. Ex 2003, pages 17-18, ¶ 38.

We also agree with Dr. Groner's conclusion, based on the first Young specification, as a whole, that one skilled in the art would not have found that Young had possession of a method for making or using a control for nucleated red blood cells or "nucleated blood cells" in general apart from white blood cells. Ex 2003, page 18, ¶ 39.

6.

Dr. Wyatt testified that a person of ordinary skill in the art would have thought of nucleated red blood cells (NRBCs) and white blood cells (WBCs) as a common genus because their detection by hematology analyzers often overlapped. Ex 1041, page 21, ¶ 159.

According to Dr. Wyatt (Ex 1041, page 23, ¶ 168):

> The [first] Young specification also specifically discusses how to make fixed red blood cells, described several times as stable or resistant to lysing … as well as unfixed red blood cells that will lyse.

In support of his position, Dr. Wyatt refers to various portions of the first Young application.

A first reference is to page 23:14-18:

> Another process for the manufacture of the leukocyte analogs that are useful in the method of this invention includes the stabilizing of human white blood cells to simulate at least one of the five subpopulations of leukocytes.

Dr. Wyatt fails to explain how the first reference describes making or using an analog for a nucleated red blood cell; the reference is facially limited to white blood cells.

A second reference is to page 28:9-14:

> Fixing of the swollen cells is important to toughen the cells membranes and to prevent degradation of the membranes. This is accomplished by contacting the cells with a solution of organic aldehyde, including monoaldehyes such as formaldehyde, or dialdehydes such as glutaraldehyde.

Dr. Wyatt fails to explain how the second reference makes reference to nucleated blood cells in general or nucleated red blood cells in particular.

A third reference is to page 38:12-15:

> As appreciated by one skilled in the art, the suspension media should have sufficient tonicity to avoid cell lysis.

Dr. Wyatt does not tell us how the third reference is a description of a method for making or using an analog for nucleated red blood cells in general or nucleated red blood cells in particular.

A fourth reference is to page 29:20-23:

> In addition, the pH affects the release of hemoglobin. If the fixation reaction occurs too quickly, the cell will not be able to leak the hemoglobin.

In some instances, analogs are made from red blood cells. *See*, *e.g.*, Examples 1 and 2 and the discussion at Ex 1003, page 23:3-8:

> the cells of avian [sic—birds], alligators and nurse sharks, are nucleated, but the presence of a nucleus is neither essential nor detrimental for their use as a substitute for human white blood cells, given the process described herein which permits a regulated hemolysis of the red blood cells.

Dr. Wyatt has not explained why the fourth reference is not a reference to how hemoglobin is removed from nucleated red blood cells used to make control analogs for white blood cells. Nowhere does Dr. Wyatt explain how the fourth reference is a description associated with making or using a control analog for nucleated red blood cells.

A fifth reference is to page 36:1-5 (Ex 1041, page 23, ¶ 168, last two lines), although we think the reference should probably be to page 35:27 through page 36:6:

> More specifically, when the control product is used in instruments, such as those that employ the Coulter Model VCS technology, which uses a reagent system such as described in U.S. Patent No. 4,751,179, in order to distinguish at least to population of leukocytes, (1) lymphoids (lymphocytes) and (2) myeloids (neutrophils, monocytes, oesinophils and basophils), the preferred suspension media enable the reaction between the

> weaker lytic reagent and the non fixed red blood cells to occur so that the red blood cells lyse while the leukocyte analogs remain substantially unaffected, enabling each type of leukocyte analog to be counted.

Dr. Wyatt has not explained why the fifth reference describes a method for making or using a control analog for nucleated red blood cells. On its face, the fifth reference facially is talking about counting leukocyte analogs (white blood cell analogs).

7.

We have considered the remaining testimony by Dr. Wyatt. What we find in that testimony is a convincing story as to why one skilled in the art, given the disclosure of the involved Young applications, if not the first Young application, would have been *enabled* to make and use analogs for nucleated red blood cells if there has otherwise been a description that making the analog would be useful. However, the written description requirement and the enablement requirement of § 112 are separate requirements. *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336 (Fed. Cir. 2005), *rehearing and rehearing in banc denied*, 433 F.3d 1373 (Fed. Cir. 2006). A disclosure which would enable one skilled in the art to make and use particular subject matter does not necessarily describe the subject matter. In this case, once someone suggests making an analog for a nucleated red blood cell and asks how would it be done, all one need do is refer to the first Young application and the remaining prior art relied and known apparatus and practices in the art, all fully detailed by Dr. Wyatt in his testimony.

But, the *first Young application* does not describe making and using a control analog for nucleated blood cells beyond *white* nucleated blood cells.

C.

Because the claims presented by Young in the first Young application were not patentable under 35 U.S.C. § 112 (written description) in that application, Young cannot claim benefit under 35 U.S.C. § 120 of the filing date of the first Young application.

Reason (2)

Claims essentially identical in all material respects to the involved Young claims were presented by Young in the first Young application. The first Young application is not "an application filed after the [Ryan] application is published." Why? Because, the first Young application was pending when the Ryan applications were published.

However, we have held that the claims which were presented did not comply, in the *first Young application*, with the written description requirements of 35 U.S.C. § 112. An issue in need of resolution with respect to Reason (2) is the following: Must a claim presented in an attempt to comply with 35 U.S.C. § 135(b)(2) also comply with the written description requirement of 35 U.S.C. § 112? We hold that it must.

Young maintains that it complied with 35 U.S.C. § 135(b)(2) by presenting the claims in the first Young application. Paper 57, page 16. Young further maintains that those claims comply with 35 U.S.C. § 112. Paper 57, page 19. Moreover, Young still further maintains that compliance with 35 U.S.C. § 112 is not necessary to comply with 35 U.S.C. § 135(b).

Paper 104. In support of its position, Young cites *In re Berger*, 279 F.3d 975 (Fed. Cir. 2002).

In our view *Berger* did not involve the issue we now address. In *Berger*, claim 7 was rejected *inter alia* under 35 U.S.C. § 135(b), but not 35 U.S.C. § 112, first paragraph. Claims 1-4, which were not rejected under § 135(b), were rejected as being indefinite under 35 U.S.C. § 112, second paragraph. We fail to appreciate how the facts in *Berger* involve the facts before us. There was no contested § 120 issue involved in resolving the § 135(b) issue.

We agree with Ryan that presentation of a claim to subject matter not described in an application should not trigger compliance with § 135(b)(2). *First*, it does not make sense. An applicant could put an "interfering" claim in any pending application and then assert that the claim had been timely filed. *Second*, the very repose which § 135(b)(2) seeks to impose would be destroyed if an interference is declared with an application which fails to describe the invention claimed in the application. *Third*, even if an interference is declared, the applicant would lose on a threshold motion for judgment based on a lack of a written description for the claimed subject matter.

For completeness, we will note that in the case before us, the Examiner had no occasion in the first Young application to look into the lack of written description because a restriction requirement was made. Ordinarily, the patentability on its merits of a claim is not reviewed when making a restriction requirement.

Reason (3)

When an application is published its claims are also published. Because, the scope of claims can change during prosecution, claims in an issued patent may be materially different from those published. For example, claims may have to be materially altered to avoid prior art cited by the Examiner. *Parks v. Fine*, 773 F.2d 1577, 1579 (Fed. Cir. 1985); *In re Berger*, 279 F.3d 975, 982-83 (Fed. Cir. 2002).

We have understood Ryan to argue that (1) whether published claim scope changes is not relevant (because Ryan says the statute does not say so) and (2), in any event, the scope of the claims in the Ryan patents is not materially different from the scope of the claims as published.

A.

We disagree with Ryan's first contention—that even if the claims of an issued patent are materially changed from any published claims, § 135(b)(2) should be applied.

If the claims of a patent are materially narrower than the claims of a published application, there would never need to be an interference involving the published claims and the need to have copied the claims becomes a moot issue. On the other extreme, if the published claims and the patent claims are the same (*i.e.*, no amendment made during prosecution), then copying the published claims within one year makes sense and an applicant would have needed to copy the claims within one year of publication to avoid the § 135(b)(2) bar.

Assuming that an applicant timely "copies" a published claim, the Examiner will not recommend, and there would be no need for, an

interference until both the published claim and the "copied" claim are patentable, including being patentable over the prior art.

There are numerous "what ifs" which come to mind with respect to examination when there is a § 135(b)(2) issue. Fortunately for all, we do not have to answer all the imaginable "what ifs" in this case. One possible "what if" may be worth considering, since it helps focus our analysis. Suppose (1) A files an application, (2) A's application is published, (3) more than one year after publication, B "copies" A's published claims, (4) since day one the Examiner has rejected A's published claims over the prior art, and (5) A has not been able to overcome the rejection. We will assume in the example, that the prior art against A does not apply to B so B is "free" of the prior art. Does the Examiner reject B under § 135(b)(2)? If so, is the rejection provisional? If A never issues, does that mean B does not get a patent even though B is patentable over the prior art? Or, does the Examiner allow B's claims upon A's application becoming abandoned? If A ultimately overcomes the prior art through material amendments and a patent issued to A, does B forfeit a patent on claims which were patentable to B over the prior art but which were (1) published and (2) unpatentable to A?

What becomes apparent from the way in which § 135(b)(2) "works" is that a cautious applicant "copies" the published claim within one year of publication and then waits to see what happens. If a patent issues, the cautious applicant also "copies" the patent claims. Here that has not occurred. Young has not timely presented claims. The claims in the involved Young application were presented more than one year after publication of the Ryan applications.

Between the extremes of (1) no amendment to the published claims prior issuance of a patent and (2) amendments that all would agree are major and substantial (*e.g.*, to avoid the prior art), there are other possible amendments. How should we treat those amendments? In our view, an amendment which adds a non-material limitation to a published claim should keep the § 135(b)(2) bar alive, whereas an amendment which is material should not. We therefore interpret § 135(b)(2) to bar a claim only if the "the claim of an application [which is] published" ultimately (1) issues as published or (2) issues with no material changes.

B.

1.

In our view, the claims of the first Ryan patent (method of making a control) do not contain material changes vis-à-vis the claims of the first Ryan applications as published. On the other hand, the claims of the second Ryan patent (method of using a control) contain material changes vis-à-vis the claims of the second Ryan application as published.

In response to our invitation to submit post-oral argument information, Ryan submitted *inter alia* Appendix 4 as part of Paper 106. Appendix 4 comprises Part A and Part B. Appendix 4 is attached to this opinion.

Part A compares the scope of the claims of the second Ryan application as published with the claims of the second Ryan patent.

Part B compares the scope of the claims of the first Ryan application as published with the claims of the first Ryan patent. Appendix 4, page A4-12 through page A4-19.

2.

Appendix 4, Part B—first published Ryan application

The amendments to published Ryan claim 2 in the first published Ryan application are revealed in Appendix 4, page A4-12-13.

It should be noted that claim 2 was a dependent claim when the first Ryan application was published. Ex 2017, page 7. It was amended to become an independent claim and ultimately issued as an independent claim. Ex 1015, col. 13.

a.

A first amendment to claim 2, as published, as the limitation "wherein said membrane maintains sufficient structural integrity to substantially surround the remaining nucleus." Appendix 4, pages A4-13 through A4-19.

Young maintains that the amendment was material and Ryan disagrees.

We agree with Ryan's observation on pages A4-12 through A4-13 of the Appendix: The addition of the phrase was an immaterial change to further clarify that the membrane remained intact around the nucleus. The limitation essentially was already present in published claim 2, though in different wording, by way of the phrases "membrane inclosing a nucleus and cytoplasm" and "stabilizing said membrane with said nucleus remaining therein." If the membrane did not have "sufficient structural integrity," it would be destroyed upon removal of cytoplasm and there would be nothing left to "stabilize."

b.

A second amendment to claim 2, as published, was "to give a product." Appendix, page A4-13. The amendment was a formal amendment to provide an antecedent in step c) for "admixing the product of step c)" step d).

c.

Other amendments to published claim 2 are likely formal and immaterial.

d.

The analysis with respect to published claim 2 is equally applicable to published independent claim 11.

3.

Appendix 4, Part A—second Ryan published application

The amendments to published Ryan independent claim 1 in the second published Ryan application are revealed in Appendix 4, pages A4-1 through A4-13.

One amendment made to published Ryan claim 1 was addition of the limitation "and wherein the cytoplasm of the stabilized blood cell has been substantially removed from within said membrane." Appendix 4, page A4-1.

Ryan concedes that the addition was made in view the Examiner's rejections over the prior art. Appendix 4, page A4-1.

No convincing explanation is presented by Ryan why the amendment is not a material change. What does Ryan have to say? To find out, we turn to pages 6-7 of Paper 106:

> During prosecution of the '137 patent [the second Ryan patent], Ryan's claims as published were rejected over prior art disclosing a control containing a nucleated blood cell wherein the source blood cell used was fixed (but no cytoplasm was removed). (Exhibit 1064, at pp.4-11) In response to this rejection, Ryan added the following limitation: "and wherein the cytoplasm of the stabilized blood cell has been substantially removed from within said membrane." (Ex 1065 at pp. 3-5 and 7-8). Though new to the claims corresponding to the '137 patent [the second Ryan patent], this limitation already existed in the published claims corresponding to the '563 patent [the first Ryan patent], which published on the same day. Nevertheless, for purposes of 135(b)(2) Ryan relies on the published claims corresponding to the '563 patent [second Ryan patent] containing this limitation (discussed below).

In our view, the claims in a first published application should not be relevant to a determination of whether an amendment to a claim in a second published application adds a material limitation. Proper notice under § 135(b)(2) should not have to turn on whether a third-party can decipher limitations in more than one application to divine what it is that the third-party must present in its application. If § 135(b)(2) is designed to give an applicant "repose," then the applicant needs to give notice of what it is that will be "reposed."

Decision on Ryan Motion 2

For the reasons given, Ryan Motion 2 is *granted* as to Interference ~~105,505~~ [105,504] and a judgment will be entered against Young (method of using a control). Ryan Motion 2 is *denied* as to Interference ~~105,504~~ [105,505] (method of making a control).

F. Ryan Motion 1

Pursuant to 37 C.F.R. § 41.125(a), we exercise discretion to consider next Ryan Motion 1.

Ryan Motion 1 seeks judgment against Young based on Young's alleged failure to comply with the written description and enablement provisions of the first paragraph of 35 U.S.C. § 112.

Scope of involved Young claims

The involved Young claims were original claims in the involved Young applications. *See* Ex 1003, Preliminary Amendment filed with application; Ex 1004, Preliminary Amendment filed application. We will note that it would be helpful to the Board and an opponent if a large exhibit has consecutive page numbers starting with 1 on the first page

When the same claims were presented in the first and second Young applications, they were presented by amendment and were not original claims.

The term "nucleated blood cells" would be understood by one skilled in the art to be a reference to both nucleated white blood cells and nucleated red blood cells.

Since "nucleated blood cells" include both nucleated white blood cells and nucleated red blood cells, the involved Young claims cover making or

using control analogs for nucleated white blood cells and nucleated red blood cells.

Written description

Original claims form part of the original specification. *In re Anderson*, 471 F.2d 1237, 1244 (CCPA 1973).

The Young disclosure explicitly describes numerous nucleated white blood species and nucleated blood cells. Nucleated blood cells include nucleated red blood cells. But, that does not take away the fact that as filed the Young involved applications describe "nucleated blood cells."

Ryan maintains that since all Young describes, by way of examples, is nucleated white blood cells that Young should not be allowed to "cover" nucleated red blood cells. In support of its argument, Ryan cites several Federal Circuit cases. Paper 69, pages 3-4. We have considered the cited case, but must note that each written description (an issue of fact) is dependent on the facts in each case. Accordingly, it will not often occur that one written description holding will control a different written description issue. *In re Driscoll*, 562 F.2d 1245, 1249 (CCPA 1977); *accord Unocal v. Atlantic Richfield Co.*, 208 F.3d 989, 1001 (Fed. Cir. 2000).

*In re Curti*s, 354 F.3d 1347, 1357-58 (Fed. Cir. 2004), involved a situation where Curtis filed a continuation-in-part and added disclosure. The continuation-in-part described a “genus of friction enhancing agents.” On the other hand an earlier parent did not describe the genus. The Federal Circuit recognized that a continuation-in-part can have additional disclosure and that what is described in the continuation-in-part may not be described in a parent application. In our view that is what has occurred in the case

before us. By virtue of having added the language “nucleated blood cell” in the involved Young applications, Young has added disclosure not present in its parent first and second Young applications. We have not overlooked the fact that Young characterizes the involved Young applications as “continuations” of the earlier first and second Young applications. Because the involved Young applications contain additional disclosure, albeit in the original claims, those applications are "continuations-in-part" of the earlier first and second Young applications. The "continuation" label is not magic; what matters is whether additional disclosure is added. Here additional disclosure was added.

Noelle v. Lederman, 355 F.3d 1343, 1350 (Fed. Cir. 2004), is similar to *In re Curtis* and involved an issue of whether a parent application described an invention claimed in a subsequent continuation-in-part. The parent description of a murine antibody did not satisfy the written description requirement for what the court referred to as human and genus antibody claims. *Noelle* did not hold the claims of the involved Noelle’s involved application as being unpatentable based on any alleged failure to comply with the written description requirement.

Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998), like the two prior cases, involved a continuation-in-part versus parent disclosure. Here we are not concerned with any parent application. The court held that the narrow language of the parent application could not be said to disclose the hemispherical shape of the claims of the patent which issued on the basis of the continuation-in-part application.

LizardTech Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1346 (Fed. Cir. 2005), *reh'g en banc denied*, 433 F.3d 1373 (Fed. Cir. 2006), holds that it is unnecessary to spell out every detail of an invention in a specification. Rather, only sufficient information must be present to convince a person having ordinary skill in the art that the inventor possessed the invention. In this case, Young not only describes numerous species of nucleated white blood cells, but "nucleated blood cells" as well. The uncontradicted evidence shows that one skilled in the art views "nucleated blood cells" as including both nucleated white blood cells and nucleated red blood cells.

Enablement

Ryan maintains, in support of its motion, that the involved Young applications do not enable one skilled in the art to make and use nucleated red blood cell controls. In presenting its argument, Ryan in effect would confine the relevant disclosure solely to the specification of the involved Young applications.

A recent Federal Circuit opinion provides a road map for analysis of the enablement issue in this case. *Sitrick v. Dreamworks, LLC*, Appeal 2007-1174 (Fed. Cir. Feb. 1, 2008). The appeal involved integrating a user's audio signal or visual image into a pre-existing video games *or* movies. The district court held patents invalid for lack of enablement as to movies, expressing no views on enablement with respect to video games. The patent claims encompassed both video games and movies. The district court found that patents did not explain how an Adaptor Interface System (IAIS) would function outside of a video game. The defendant's experts did not believe

disclosure regarding video games would enable use of the IAIS in movies. The Federal Circuit held that the full scope of a claimed invention must be enabled. As noted by the Federal circuit, enabling the full scope of each claim is part of the *quid pro quo* of the patent bargain. Accordingly, because the claims cover both movies and video games, the patents must enable both embodiments. An enablement analysis begins with the specification. The Federal Circuit agreed with the district court that the patents in suit did not describe how the substitution and integration of a user image would be accomplished in movies. The defendant's experts explained that one skilled in the art would not have been able to take the teachings regarding video games and apply them to movies. Lastly, the Federal Circuit noted that enablement is determined from the vantage point of one skilled in the art.

The very considerations which lead *Sitrick* to agree with the district court concerning lack of enablement as to movies, leads us to a contrary conclusion in this case with respect to nucleated red blood cells. Initially, we will note that Ryan does not challenge enablement with respect to nucleated white blood cells. Ryan's "beef" is that Young does not enable nucleated red blood cells. The claims here, like those in Sitrick, cover two embodiments: making and using control analogs for both nucleated white blood cells and nucleated red blood cells. In this case, just as the district court found that patents do not explain how IAIS would function outside of a video game, we conclude that the involved Young applications do not *explicitly* tell one skilled in the art how to make and use control analogs for nucleated red blood cells. Where this case differs from Sitrick is that whereas defendant's experts did not believe disclosure regarding video

games would enable use of the IAIS in movies, here one skilled in the art, given the Young disclosure, would have been enabled to make and use control analogs for nucleated red blood cells. Accordingly, unlike Sitrick, the full scope of a claimed invention is enabled. While an enablement analysis begins with the specification, the analysis includes what is known in the art and what one skilled in the art would know how to do given a disclosure in a specification. *Webster Loom Co. v. Higgins*, 15 Otto (105 U.S.) 580, 586 (1881) (an inventor may begin a description of an invention at the point where his invention begins, and describe what he has made that is new, and what it replaces of the old; that which is common and known is as if it were written out in the patent and delineated in the drawings). In *Sitrick*, the defendant's experts convincingly explained that one skilled in the art would not be able to take the teachings regarding video games and apply them to movies. However, in this case, Dr. Wyatt has explained why the teachings of Young enable making and using control analogs for nucleated red blood cells. We accept his enablement testimony and explanation.

For example, Ryan argues that the apparatus described in the involved Young application would not be used by one skilled in the art to analyze nucleated red blood cells. Dr. Wyatt has a satisfactory answer to Ryan's argument. Ex 1041, page 21, ¶ 159 *et seq*. In this respect, we note that Dr. Wyatt's position is supported by prior art literature.

See, *e.g.*, Ex 1041, page 22, ¶¶ 161 and 163.

With respect not only to enablement, but the written description issue, Ryan maintains that the art is unpredictable. Specifically, Ryan seems to be

of the view that what works with nucleated white blood cells will not work with nucleated red blood cells. In our view, Dr. Wyatt answers Ryan's concern. *See, e.g.*, Ex 1041, page 29, ¶ 202 *et seq*. Dr. Wyatt also tells us that the level of skill in the art is relatively high and that one skilled in the art knows how to use the various analytical tools known in the art.

Observations

Some observations about the case before us are believed to be in order, particularly what Ryan has not alleged, and cannot now allege.

First, Ryan has not moved to deny Young earlier constructive reductions to practice accorded to Young in the declaration. Perhaps no motion was filed because Ryan recognizes that Young describes nucleated white blood cell species and an earlier constructive reduction to practice can be based on a single enabling description of an embodiment within the scope of the count.

Second, Ryan did not move for judgment based on unpatentability over the prior art. Ryan could have maintained that the claims in the involved first and second Young applications are not entitled to benefit of the first and second Young applications under 35 U.S.C. § 120. The prior art would have been any prior art, including prior Young patents, which would be prior art under § 102(b). But, Ryan did not timely seek authorization to file such a motion and therefore patentability of the involved Young claims over the prior art is not before us. *Cf. Brand v. Miller*, 487 F.3d 862, 869 (Fed. Cir. 2007) (in an interference the Board's role is one of an impartial adjudicator of an adversarial dispute between two parties). We decline to consider in these interferences the patentability over

the prior art of the involved Young claims. The Examiner will be free to consider patentability when the Young applications return to *ex parte* prosecution after the interferences.

Decision on Ryan Motion 1

For the reasons given, Ryan Motion 1 is denied.

G. Young motion 1

Young Motion 1 seeks judgment against Ryan based on alleged unpatentability over the prior art.

We decline at this time to reach the motion.

With respect to Interference 105,505, a judgment is being entered against Young for failure to comply with the requirements of 35 U.S.C. § 135(b)(2). Since § 135(b)(2) is a statute of repose, in our view Young no longer has standing in the interference. Our decision not to reach Young Motion 1 with respect the Ryan patent involved in Interference 105,505 is without prejudice to Young seeking reexamination of the claims of the patent on the basis of the prior art relied upon and cited in its motion.

With respect to Interference 105,504, we have denied Ryan Motion 2 based on alleged repose under 35 U.S.C. § 135(b)(2). We have also denied Ryan Motion 1 based on alleged non-compliance with the first paragraph of 35 U.S.C. § 112.

Ordinarily, we might proceed to consider Young Motion 1. However, we note an over five-year difference in constructive reductions to practice accorded to the parties. While Ryan maintains in its priority statement that it conceived and actually reduction to practice before Young's earliest accorded date, Ryan will not only have to establish its case, but will be faced

with explaining why it did not suppress or conceal the invention over a four-year period prior to filing its application. Alternatively, Ryan will have to explain why it was diligent from for the five years prior to Young's accorded dates until Ryan's constructive reduction to practice.

While we will not prejudge priority, it would appear that Ryan has a substantial hurdle to overcome. Accordingly, we exercise our discretion to proceed to priority and allow Ryan to put on its case. We note that Young did not file a priority statement, so Young is restricted to its earliest accorded date.

If Ryan prevails on priority, then we will take up Young Motion 1. If Ryan does not prevail on priority, then patentability over the prior art becomes moot.

H. Motions to exclude evidence

Ryan Miscellaneous Motion 4

Ryan seeks exclusion of (1) Ex 1033, (2) Ex 1036, (3) Ex 1039, (4) Ex 1051, (5) Ex 1073, and (6) Ex 1093. Since we have not considered or relied on these exhibits, Ryan's motion to exclude is *dismissed* as moot.

Young Miscellaneous Motion 5

Young seeks exclusion of (1) Ex 2060 (¶¶62-63), (2) Ex 2063, (3) Ex 2070 through Ex 2077, (4) Ex 2083, (5) Ex 2107 (¶¶ 4-5, 24-30, 38-40), and (6) Ex 2109. Since we have not considered or relied on these exhibits, Young's motion to exclude is *dismissed* as moot.

I. Young Miscellaneous Motion 4

Young Miscellaneous Motion 4 (Paper 77) seeks entry of an order striking Ryan Reply 1 (Paper 69).

According to Young, in Ryan Reply 1, Ryan seeks to file a motion for judgment against Young based on 35 U.S.C. § 103. In the reply, Ryan suggests that if certain arguments of Young are accepted, then Young the involved Young claims are unpatentable over the prior art.

Ryan did not obtain authorization to file a motion for judgment against Young based on the prior art. We have considered the statements in the reply only as argument. As noted earlier in this opinion, we have not considered whether the involved Young claims are unpatentable over the prior art because Ryan did not timely seek, and has not timely raised, the issue of whether the involved Young claims are unpatentable over the prior art.

Since we have not considered on the merits the portion of Ryan Reply 1 which Young finds objectionable, we will *dismiss* Young Miscellaneous Motion 4 as moot.

Our dismissal should not be construed as precluding the Examiner from rejecting the involved Young claims on the ground suggested in Ryan Reply 1 when *ex parte* prosecution is resumed.

J. Young Responsive Motion 3

Young Responsive Motion 3 proposes to add claims to the involved Young applications in the event Ryan Motion 1 is granted. Since Ryan Motion 1 is being denied, there is no need to consider Young Responsive Motion 1. Young Responsive Motion is therefore *dismissed*.

K. Order

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

ORDERED that Ryan Motion 1 seeking judgment based on the first paragraph of 35 U.S.C. § 112 is *denied* as to both Interference 105,504 and Interference 105,505.

FURTHER ORDERED that Ryan Motion 2 for judgment based on repose under 35 U.S.C. § 135(b)(2) is ~~*granted*~~ [*denied*] as to Interference 105,505 and is ~~*denied*~~ [granted] as to Interference 105,504.

FURTHER ORDERED that further consideration of Young Motion 1 alleging unpatentability over the prior art is *deferred* until the priority phase of Interference ~~105,504~~ [105,505].

FURTHER ORDERED that Young Motion 3 for leave to add claims to the involved Young applications is *dismissed* because Ryan Motion 1 has been denied.

FURTHER ORDERED that Ryan Miscellaneous Motion 4 to exclude evidence is *dismissed* as moot.

FURTHER ORDERED that Young Miscellaneous Motion 4 to strike Ryan Reply 1 is *dismissed* as moot.

FURTHER ORDERED that Young Miscellaneous Motion 5 to exclude evidence is *dismissed* as moot.

FURTHER ORDERED that a copy of this [AMENDED] DECISION ON MOTIONS shall be placed in the file of Interference 105,504 and the file of Interference 105,505.

FURTHER ORDERED that a copy of this [AMENDED] DECISION ON MOTIONS shall be placed in the files of (1) Ryan Patent 6,723,563 B2, (2) Ryan Patent 6,653,137 B2, (3) Young 10/909,561, and (4) Young application 10/909,594.

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