



Board of Patent Appeals
and Interferences

Informative

Opinion

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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.

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

4
5 *McKELVEY, Senior Administrative Patent Judge.*

6
7

[AMENDED] DECISION ON MOTIONS

1 **A. Statement of the case**

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

3 Oral argument was held on 19 September 2007. On 27 September
4 2007, an order was entered inviting the parties to submit additional briefing.
5 Paper 100. On 29 October 2007, the parties timely responded to the
6 invitation. Paper 104; Paper 106. Supplemental oral argument took place
7 on 01 November 2007. We express our gratitude to counsel, and their
8 respective clients, for responding to our invitation for additional briefing
9 and for attending the supplemental oral argument.

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

12 Interference 105,504—Method of making control

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

14 The interference is between:

- 15 (1) Junior Party Wayne L. Ryan, based on U.S. Patent
16 6,723,563 B2, issued 20 April 2004 (**first Ryan patent**),
17 based on application 10/005,999, filed 03 December
18 2001 (**first Ryan application**), and
19 (2) Senior Party (a) Carole J. Young, (b) Michael N. Elliott,
20 (c) Nancy R. Naylor-Schlipp and (d) Timothy J. Fischer,
21 based on application 10/909,561, filed 02 August 2004
22 (**first involved Young application**).

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

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

25 Count 1 is the only count:

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1 A method according to (1) any of claims 1, 2, 11 or 20 of
2 Ryan U.S. Patent 6,723,563 B2 or (2) any of claims 41, 50, 60,
3 69 or 86 of Young application 10/909,561.

4 Ryan claim 1

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

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

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

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

17 Young claim 41

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

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

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

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- 1 c) stabilizing said membrane with said nucleus
2 remaining therein to give a product; and
3 d) admixing the product of step c) in a suspension
4 medium suitable for delivering said product of step c to a
5 hematology analyzer for analysis.

6 The claims of the parties are:

- 7
8 Ryan: 1-20
9 Young: 41-54, 60-73 and 86-87

10
11 The claims of the parties that correspond to Count 1 are:

- 12
13 Ryan: 1-20
14 Young: 41-54, 60-73 and 86-87

15
16 The claims of the parties that do not correspond to Count 1 are:

- 17
18 Ryan: None
19 Young: None

20
21 The parties have been accorded the following earlier constructive
22 reductions to practice (*i.e.*, benefit for the purpose priority) for Count 1:

- 23
24 Ryan: None
25 Young: Application 10/214,717, filed 09 August 2002
26
27 Application 08/787,408, filed 22 January 1997,
28 now U.S. Patent 6,509,192, issued 21 January 2003.
29
30 Application 08/432,435, filed 28 April 1995.

31

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1 Young is Senior Party based on its accorded priority date of 28 April
2 1995, which is over five years prior to Ryan's earliest date which is
3 03 December 2001.

4 Interference 105,505—Method using a control

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

7 The interference is between:

- 8 (1) Junior Party Wayne L. Ryan, based on U.S. Patent
9 6,653,137 B2, issued 25 November 2003 [**second Ryan**
10 **patent**], based on application 10/007,519, filed
11 03 December 2001 [**second Ryan application**], and
12 (2) Senior Party (a) Carole J. Young, (b) Michael N. Elliott,
13 (c) Nancy R. Naylor-Schlipp and (d) Timothy J. Fischer,
14 based on application 10/909,594, filed 02 August 2004
15 [**second involved Young application**].

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

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

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

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

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

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

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

5 Count 2 is the only count (Paper 39):

6 A method according to (1) any of claims 1, 5, 9 or 13 of Ryan
7 U.S. patent 6,653,137 B2 or (2) any of claims 43, 49, 51, 54,
8 59-60, 62-64, 67, 69 or 72-75 of Young application 10/909,594.

9 The claims of the parties are:

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

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

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

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

18 Ryan: None
19 Young: None

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

23
24 A method of using a control including a nucleated red
25 blood cell component comprising the steps of:

26 a) providing a control including a stabilized blood cell
27 suitable for simulating a nucleated red blood cell, the stabilized
28 blood cell including a membrane enclosing a nucleus and

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

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

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

9 d) reporting nucleated red blood cells in said control.

10
11 Young claim 69 [replacing Young claim 40]

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

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

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

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

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

3
4 The parties have been accorded the following earlier constructive
5 reductions to practice (*i.e.*, benefit for the purpose of priority) for Count 2:

6
7 Ryan: None

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

9
10 Application 08/787,408, filed 22 January 1997,
11 now U.S. Patent 6,509,192, issued 21 January 2003.

12
13 Application 08/432,435, filed 28 April 1995.
14

15 Young is Senior Party based on its accorded priority date of 28 April
16 1995, which is over five years prior to Ryan's earliest date which is 03
17 December 2001.

18 Motions

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

21 Ryan Motion 1

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

26 Ryan Motion 2

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

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1 35 U.S.C. § 135(b)(2). Young timely opposed (Paper 57). Ryan timely
2 replied (Paper 70).

3 Ryan Miscellaneous Motion 4

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

6 1033,
7 1036,
8 1039,
9 1051,
10 1073 and
11 1093

12
13 all filed by Young. Young timely opposed (Paper 89). Ryan timely replied
14 (Paper 91).

15 Young Motion 1

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

19 Young Responsive Motion 3

20 Young Responsive Motion 3 (Paper 36) is a responsive motion to
21 Ryan Motion 1. Proposed Young claim 88 would be added to involved
22 Young application 10/909,561. Proposed Young claim 76 would be added
23 to involved Young application 10/909,594. Ryan timely opposed (Paper
24 59), maintaining that the motion should not be granted because proposed
25 claims 88 and 76 do not comply with (1) the written description and
26 enablement requirements of 35 U.S.C. § 112 and (2) the provisions of
27 35 U.S.C. § 135(b)(2). Young timely replied (Paper 68).

1 Young Miscellaneous Motion 4

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

6 Young Miscellaneous Motion 5

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

9 2060 (¶¶62-63),
10 2063,
11 2070 through 2077,
12 2083,
13 2107 (¶¶ 4-5, 24-30, 38-40), and
14 2109

15
16 all filed by Ryan. Ryan timely opposed (Paper 88). Young timely replied
17 (Paper 90).

18 **B. Interference motion practice**

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

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

23 (1)

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

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

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

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

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

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

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

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

22 (2)

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

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

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

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

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

13 Board practice allows the Board to allocate resources by assigning one
14 panel judge to one motion and another panel judge to another motion.

15 *Cf.* Interference 105,402 where an opinion resolving one set of motions was
16 authored by one judge (Int. 105,402, Paper 114) and an opinion resolving
17 a different set of motions was authored by another judge (Int. 105,402,
18 Paper 115). *Cf. Joy Technologies, Inc. v. Quigg*, 12 USPQ2d 1112 (D.D.C.
19 1989) (Judge Gasch decided question of whether jury trial available in civil
20 action under 35 U.S.C. § 145) and *Joy Technologies, Inc. v. Manbeck*,
21 17 USPQ2d 1257 (D.D.C. 1990) (Judge Bennett decided patentability on the
22 merits).

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

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

3

4 **C. Background of technology**

5

Blood cells

6 Blood is a suspension of small, highly concentrated cells in plasma.

7 Paper 32, page 3; Ex 2003, ¶ 9.

8 Blood includes white blood cells and red blood cells.

9 Red blood cells are known as "erythrocytes."

10 White blood cells are known as "leukocytes."

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

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

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

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

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

24 The non-mammal animals include fish, amphibians, reptiles and birds,
25 whose red blood cells are larger than mammalian red blood cells.

26 Ex 2003, ¶ 12; Ex 2007.

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

3 Hematology

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

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

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

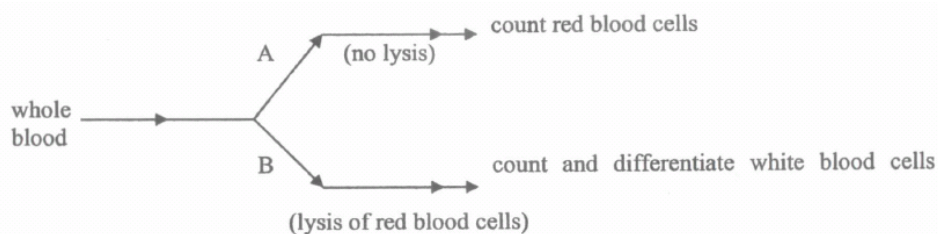
11 To confirm the accuracy of measurements, it is necessary to have
12 quality control materials that simulate a blood specimen.

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

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

18 A control may have more than one analog.

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



21

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

3 The sample is split into parallel channels A and B.

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

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

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

15 **D. Level of skill in the art**

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

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

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

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

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

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

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

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

10 Educational degrees in and of themselves often do not tell us much.
11 *Argyropoulos v. Swarup*, 56 USPQ2d 1795, 1807 (Bd. Pat. App. & Int.
12 2000) (explaining why defining the level of skill in the art in terms of
13 degrees obtained is less helpful than defining it in terms of what such a
14 person would have known and what the person would have been able to do).

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

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

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

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

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

6 The person would not have been a mere technician following the
7 instructions of others for making and using controls. Ex 1041, ¶ 232. In
8 other words, to quote *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct.
9 1727, 1742 (2007), the person would not be an "automaton".

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

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

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

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

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

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

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

13 As a result of the Examiner's requirement for restriction, Young
14 elected to prosecute the invention of claim 81 in involved Young application
15 10/909,561, which previously had been filed on 02 August 2004. Ex 1003.

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

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

20 As noted earlier, Young filed the first Young application on
21 09 August 2002. Ex 1069, page 1.

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

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

- 1 A method of using a hematology control product
2 including at least one nucleated blood cell analog comprising
3 the steps of:
- 4 a) providing a hematology control product including a
5 nucleated blood cell analog, wherein the analog is a blood cell
6 including a membrane enclosing a nucleus and hemoglobin,
7 wherein the blood cell has been treated so that said membrane
8 is resistant to degradation, and wherein 20% to 80% by weight
9 of the hemoglobin in the blood cell has been removed;
 - 10 b) providing an instrument for analyzing a blood cell
11 sample by at least two physical properties selected from the
12 group *comprising* DC volume, RF size, opacity, and light
13 scatter;
 - 14 c) passing the control product through the instrument for
15 detection of said nucleated blood cell analog; and
 - 16 d) reporting said nucleated blood cell analog in the
17 control product.

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

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

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

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

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

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

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

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1 A chronological summary of events follows:

- 2 1. 12-03-2001 First Ryan application filed
- 3 12-03-2001 Second Ryan application filed
- 4
- 5 2. 08-09-2002 First Young application 10/214,717 filed
- 6
- 7 3. 06-05-2003 First Ryan application published
- 8 06-05-2003 Second Ryan application published
- 9
- 10 4. 11-25-2003 Second Ryan patent issued
- 11
- 12 5. 04-20-2004 First Ryan patent issued
- 13
- 14 6. 08-02-2004 Involved Young application 10/909,561 filed
- 15 08-02-2004 Involved Young application 10/909,594 filed
- 16
- 17 7. 10-08-2004 Claims presented in first Young application
- 18
- 19 8. 12-28-2004 Restriction required in first Young application
- 20

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

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

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

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1 Analysis

2 Section 135(b) (2) reads:

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

8 Young maintains that it should prevail for three reasons.

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

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

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

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

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1 Reason (1)

2 A.

3 Ryan maintains that the statutory language "in an application filed
4 after" precludes applying the provisions of 35 U.S.C. § 120 to that
5 application for the purpose of evaluating compliance with 35 U.S.C.
6 § 135(b) (2). We disagree. *See Ding v. Singer*, Interference 105,436,
7 Paper 36, pages 8-13) (Bd. Pat. App. & Int. 2007) (available at
8 [https://acts.uspto.gov/ifiling/PublicView.jsp?identifier=105436&identifier2=
9 null&tabSel=4&action=filecontent&replyTo=PublicView.jsp](https://acts.uspto.gov/ifiling/PublicView.jsp?identifier=105436&identifier2=null&tabSel=4&action=filecontent&replyTo=PublicView.jsp) followed by
10 inserting the interference number, clicking on file contents and clicking on
11 Document 56).

12 The first sentence of § 120 states in relevant part:

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

18
19 The portions of § 120 dealing with same inventors and copendency have not
20 been quoted. The Young inventors are the same and there has been no
21 suggestion of a lack of copendency.

22 The starting point for interpreting a statute is the language of the
23 statute. *United States v. Goodyear Tire and Rubber Co.*, 493 U.S. 132, 138
24 (1969); *Kelly v. Robinson*, 479 U.S. 36, 43(1986). Words in a statute will be
25 interpreted as having their ordinary, contemporary and common meanings.
26 *Perrin v. United States*, 444 U.S. 37, 42 (1979). Statutes relating to the

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1 same thing ought to be taken into consideration in construing any one of
2 them, and it is a rule of law that all statutes *in pari materia* are to be taken
3 together, as if they were one law. *United States v. Freeman*, 3 How.
4 (44 U.S.) 556, 564 (1845). A reading of a statute that would lead to absurd
5 results is to be avoided when it can be given a reasonable application
6 consistent with its words. *Haggar Co. v. Helvering*, 308 U.S. 389, 394
7 (1940).

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

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

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

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

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

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

21 B.

22 1.

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

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

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

20

2.

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

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

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

15 3.

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

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

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

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

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

14 Starting with the summary of the invention (Ex 1003, numbered
15 page 12—note that the first two pages of Ex 1003 are not page numbered),
16 Dr. Groner notes, and we agree, that summary discusses a method for
17 making and using an analog for a white blood cell. Ex 2003, pages 8-10,
18 ¶ 25.

19 No nucleated red blood cell is mentioned in the summary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 Fixing of the swollen cells is important to toughen the cells
13 membranes and to prevent degradation of the membranes. This
14 is accomplished by contacting the cells with a solution of
15 organic aldehyde, including monoaldehydes such as
16 formaldehyde, or dialdehydes such as glutaraldehyde.

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

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

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

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

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

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

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

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

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

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

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

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

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

9 7.

10 We have considered the remaining testimony by Dr. Wyatt. What we
11 find in that testimony is a convincing story as to why one skilled in the art,
12 given the disclosure of the involved Young applications, if not the first
13 Young application, would have been *enabled* to make and use analogs for
14 nucleated red blood cells if there has otherwise been a description that
15 making the analog would be useful. However, the written description
16 requirement and the enablement requirement of § 112 are separate
17 requirements. *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d
18 1336 (Fed. Cir. 2005), *rehearing and rehearing in banc denied*, 433 F.3d
19 1373 (Fed. Cir. 2006). A disclosure which would enable one skilled in the
20 art to make and use particular subject matter does not necessarily describe
21 the subject matter. In this case, once someone suggests making an analog
22 for a nucleated red blood cell and asks how would it be done, all one need do
23 is refer to the first Young application and the remaining prior art relied and
24 known apparatus and practices in the art, all fully detailed by Dr. Wyatt in
25 his testimony.

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

3 C.

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

8 Reason (2)

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

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

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

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1 Paper 104. In support of its position, Young cites *In re Berger*, 279 F.3d
2 975 (Fed. Cir. 2002).

3 In our view *Berger* did not involve the issue we now address. In
4 *Berger*, claim 7 was rejected *inter alia* under 35 U.S.C. § 135(b), but not
5 35 U.S.C. § 112, first paragraph. Claims 1-4, which were not rejected under
6 § 135(b), were rejected as being indefinite under 35 U.S.C. § 112, second
7 paragraph. We fail to appreciate how the facts in *Berger* involve the facts
8 before us. There was no contested § 120 issue involved in resolving the
9 § 135(b) issue.

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

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

1 Reason (3)

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

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

12 A.

13 We disagree with Ryan's first contention—that even if the claims
14 of an issued patent are materially changed from any published claims,
15 § 135(b)(2) should be applied.

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

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

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

3 There are numerous "what ifs" which come to mind with respect to
4 examination when there is a § 135(b)(2) issue. Fortunately for all, we do not
5 have to answer all the imaginable "what ifs" in this case. One possible
6 "what if" may be worth considering, since it helps focus our analysis.

7 Suppose (1) A files an application, (2) A's application is published, (3) more
8 than one year after publication, B "copies" A's published claims, (4) since
9 day one the Examiner has rejected A's published claims over the prior art,
10 and (5) A has not been able to overcome the rejection. We will assume in
11 the example, that the prior art against A does not apply to B so B is "free" of
12 the prior art. Does the Examiner reject B under § 135(b)(2)? If so, is the
13 rejection provisional? If A never issues, does that mean B does not get a
14 patent even though B is patentable over the prior art? Or, does the Examiner
15 allow B's claims upon A's application becoming abandoned? If A ultimately
16 overcomes the prior art through material amendments and a patent issued to
17 A, does B forfeit a patent on claims which were patentable to B over the
18 prior art but which were (1) published and (2) unpatentable to A?

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

1 2.

2 Appendix 4, Part B—first published Ryan application

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

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

9 a.

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

13 Young maintains that the amendment was material and Ryan
14 disagrees.

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

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1 b.

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

6 c.

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

9 d.

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

12 3.

13 Appendix 4, Part A—second Ryan published application

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

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

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

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

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1 During prosecution of the '137 patent [the second Ryan
2 patent], Ryan's claims as published were rejected over prior art
3 disclosing a control containing a nucleated blood cell wherein
4 the source blood cell used was fixed (but no cytoplasm was
5 removed). (Exhibit 1064, at pp.4-11) In response to this
6 rejection, Ryan added the following limitation: "and wherein
7 the cytoplasm of the stabilized blood cell has been substantially
8 removed from within said membrane." (Ex 1065 at pp. 3-5 and
9 7-8). Though new to the claims corresponding to the '137
10 patent [the second Ryan patent], this limitation already existed
11 in the published claims corresponding to the '563 patent [the
12 first Ryan patent], which published on the same day.
13 Nevertheless, for purposes of 135(b)(2) Ryan relies on the
14 published claims corresponding to the '563 patent [second Ryan
15 patent] containing this limitation (discussed below).

16
17 In our view, the claims in a first published application should not be
18 relevant to a determination of whether an amendment to a claim in a second
19 published application adds a material limitation. Proper notice under
20 § 135(b)(2) should not have to turn on whether a third-party can decipher
21 limitations in more than one application to divine what it is that the third-
22 party must present in its application. If § 135(b)(2) is designed to give an
23 applicant "repose," then the applicant needs to give notice of what it is that
24 will be "reposed."

1 Decision on Ryan Motion 2

2 For the reasons given, Ryan Motion 2 is *granted* as to Interference
3 ~~105,505~~ [105,504] and a judgment will be entered against Young (method of
4 using a control). Ryan Motion 2 is *denied* as to Interference ~~105,504~~
5 [105,505] (method of making a control).

6
7 **F. Ryan Motion 1**

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

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

13 Scope of involved Young claims

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

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

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

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

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

3 Written description

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

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

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

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

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

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

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

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

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

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1 games would enable use of the IAIS in movies, here one skilled in the art,
2 given the Young disclosure, would have been enabled to make and use
3 control analogs for nucleated red blood cells. Accordingly, unlike *Sitrick*,
4 the full scope of a claimed invention is enabled. While an enablement
5 analysis begins with the specification, the analysis includes what is known in
6 the art and what one skilled in the art would know how to do given a
7 disclosure in a specification. *Webster Loom Co. v. Higgins*, 15 Otto
8 (105 U.S.) 580, 586 (1881) (an inventor may begin a description of an
9 invention at the point where his invention begins, and describe what he has
10 made that is new, and what it replaces of the old; that which is common and
11 known is as if it were written out in the patent and delineated in the
12 drawings). In *Sitrick*, the defendant's experts convincingly explained that
13 one skilled in the art would not be able to take the teachings regarding video
14 games and apply them to movies. However, in this case, Dr. Wyatt has
15 explained why the teachings of Young enable making and using control
16 analogs for nucleated red blood cells. We accept his enablement testimony
17 and explanation.

18 For example, Ryan argues that the apparatus described in the involved
19 Young application would not be used by one skilled in the art to analyze
20 nucleated red blood cells. Dr. Wyatt has a satisfactory answer to Ryan's
21 argument. Ex 1041, page 21, ¶ 159 *et seq.* In this respect, we note that
22 Dr. Wyatt's position is supported by prior art literature.
23 *See, e.g.*, Ex 1041, page 22, ¶¶ 161 and 163.

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

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

6 Observations

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

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

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

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

4 Decision on Ryan Motion 1

5 For the reasons given, Ryan Motion 1 is denied.

6 **G. Young motion 1**

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

9 We decline at this time to reach the motion.

10 With respect to Interference 105,505, a judgment is being entered
11 against Young for failure to comply with the requirements of 35 U.S.C.
12 § 135(b)(2). Since § 135(b)(2) is a statute of repose, in our view Young no
13 longer has standing in the interference. Our decision not to reach Young
14 Motion 1 with respect the Ryan patent involved in Interference 105,505 is
15 without prejudice to Young seeking reexamination of the claims of the
16 patent on the basis of the prior art relied upon and cited in its motion.

17 With respect to Interference 105,504, we have denied Ryan Motion 2
18 based on alleged repose under 35 U.S.C. § 135(b)(2). We have also denied
19 Ryan Motion 1 based on alleged non-compliance with the first paragraph of
20 35 U.S.C. § 112.

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

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

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

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

13 **H. Motions to exclude evidence**

14 Ryan Miscellaneous Motion 4

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

18 Young Miscellaneous Motion 5

19 Young seeks exclusion of (1) Ex 2060 (¶¶62-63), (2) Ex 2063,
20 (3) Ex 2070 through Ex 2077, (4) Ex 2083, (5) Ex 2107 (¶¶ 4-5, 24-30,
21 38-40), and (6) Ex 2109. Since we have not considered or relied on these
22 exhibits, Young's motion to exclude is *dismissed* as moot.

23 **I. Young Miscellaneous Motion 4**

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

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

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

12 Since we have not considered on the merits the portion of Ryan Reply
13 1 which Young finds objectionable, we will *dismiss* Young Miscellaneous
14 Motion 4 as moot.

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

18 **J. Young Responsive Motion 3**

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

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1 **K. Order**

2 Upon consideration of the record, and for the reasons given, it is
3 ORDERED that Ryan Motion 1 seeking judgment based on the
4 first paragraph of 35 U.S.C. § 112 is *denied* as to both Interference 105,504
5 and Interference 105,505.

6 FURTHER ORDERED that Ryan Motion 2 for judgment based
7 on repose under 35 U.S.C. § 135(b)(2) is ~~granted~~ [*denied*] as to Interference
8 105,505 and is ~~denied~~ [*granted*] as to Interference 105,504.

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

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

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

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

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

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1 FURTHER ORDERED that a copy of this [AMENDED]
2 DECISION ON MOTIONS shall be placed in the file of Interference
3 105,504 and the file of Interference 105,505.

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

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