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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CCC

Appeal 9x-xxxx
Application xx/xxx, xxx

ON BRIEF

Before: WINTERS and WILLIAM F. SMITH, Administrative Patent Judges, and MCKELVEY, Senior Administrative Patent Judge.

[Principal opinion omitted]

McKelvey, Senior Administrative Patent Judge, concurring.

I fully agree with the principal opinion, join therein and have signed it. This concurring opinion is really a request for counsel to help educate us on highly technical matters which come before this board in appeals and interferences. Any help will assist us in rendering cogent decisions and reduce the backlog of ex parte cases pending before this board.

A. Introduction

I think a somewhat sad state of affairs has developed with respect to certain cases involving highly technical issues reaching this board--especially in biotechnology cases. This sad state of affairs in biotechnology cases often can be laid to the use of "gobbledegook a la biotechese" and failure of counsel to educate us at some minimal level on the biotechnology involved. Any help which the examiner can add would also be appreciated.

B. The sad state of affairs and the way out for counsel explained

The rules provide that "[t]he application, any amendments or corrections thereto, and the oath or declaration must be in the English language ***." 37 CFR § 1.52(a). In my opinion, Commissioner Lehman should give serious consideration to amending Rule 52(a) to require that the noted papers "must be plain English."

Why the biotechnology field decided to adopt "gobbledegook a la biotechese" as its mother language instead of English is a

mystery to me. Moreover, it appears that counsel for applicants generally assume--erroneously in my case--that most members of the board are biotechnology savvy, i.e, are "experts" or, at a minimum are well-versed in "biotechese." Believe me, I am no expert and I have to put in considerable effort and time to understand a good bit of the "biotechese" which comes before me.

Consistent with the "Serenity Prayer,"¹ I have come to "accept the things I cannot change." Stated in other words, I will assume that I will have to live with "biotechese" with or without the "gobbledegook." But maybe there is something I can do to help counsel help me live with the seemingly well-established practice involving the use of "biotechese" which has become so entrenched in biotechnology patent matters before the Patent and Trademark Office. Perhaps through the words and schematic illustrations which follow, I can have some positive effect on how "biotechese" can best be presented in matters which reach this board.

An applicant in an appeal has a burden (however minimal) to show me that the examiner committed reversible error.² A party in an interference has the burden of proof if the party seeks to change the status quo with a motion³ or, on the issue of

¹ "God grant me the Serenity to accept the things I cannot change; Courage to change the things I can; and Wisdom to know the difference."

² See, e.g., 37 CFR § 1.192(c)(8)(iv), which requires the applicant in an appeal brief to "specify the errors in the rejection ***."

³ 37 CFR § 1.637(a), first sentence.

priority, if the party is the junior party.⁴ If counsel fails to educate me as to what is going on and as a result I fail to understand the case, there is a very good chance that counsel will not be able to sustain the necessary burden. Stated in other terms, if I do not know why I am reversing an examiner or why I am granting a motion in an interference, perhaps I should vote to affirm the examiner or deny the motion.

I am neither an "expert" nor a "person having ordinary skill in biotechnology." Nor does the statute require that I be an expert or a person having ordinary skill in biotechnology. All the statute says is that I should be a person of "scientific ability." 35 U.S.C. § 7, first paragraph. I will assume that I am a person of "scientific ability" given my degree in chemical engineering and understanding of organic chemistry and other engineering subjects acquired through many years of experience in cases in the Patent and Trademark Office. Throughout my experience in this agency I have been fortunate to have been educated on the job by some truly gifted scientists, many of whom are members of this board. What all this means is that if a scientific matter is explained to me in plain English, I should--and probably will--be able to understand the matter sufficiently to make an informed decision as to whether an examiner has erred or whether a party in an interference has sustained its burden with respect to a scientific issue.

Counsel should try to put themselves in our position and

⁴ 37 CFR § 1.657(a).

should assume that they have some obligation to minimally educate us in appeals and interferences before this board. I know counsel can do it because during my tenure as associate solicitor (1970-1974), deputy solicitor (1986-1988) and solicitor (1988-1994) of this agency, the Office of the Solicitor often attempted to provide simplified explanations of scientific matters for the judges of our reviewing court, not all of whom have engineering or scientific backgrounds. An example appears in the brief filed on behalf of the Commissioner in In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). A copy of the relevant part of the Vaeck brief appears as an Appendix.

C. My explanation of what I think the invention involved in this case is all about

1. Explanation using words

Claim 1 on appeal is as follows:

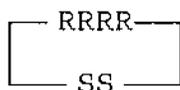
An in vivo process for producing disulfide-bonded recombinant proteins, comprising:

- (a) coexpressing protein disulfide isomerase with one or more recombinant genes encoding one or more disulfide-bonded proteins other than protein disulfide isomerase in a recombinant host.

One cannot help but see that there is a step (a), but no step (b). When I see a step identified as step (a), the first thing I look for is a step (b) and possibly a step (c), step (d) and so forth. I note that original claim 1 had a step (b).

I have no idea why in vivo is in the claim. After all, I thought that to "express" (biotechese for "make") something, certain biological action had to take place in a living organism. Isn't that why we find at the end of the claim the "recombinant host" language?

Then, of course, we have a "recombinant" gene (biotechese for genetically engineered gene) which is "encoding" (more biotechese for "make"). But, if I understand this case correctly, the recombinant gene in the "recombinant host" (biotechese for genetically engineered host) does not make "disulfide-bonded proteins." What the gene makes is a protein which has a thiol group (-SH, also known as a mercapto group), which becomes a disulfide-bonded protein within the yeast cell. "Protein disulfide isomerase" is biotechese for a composition of matter which will catalyze the reaction of a thiol group (-SH) on one compound with another thiol group on the same (HS-RRRR-SH) or another (R₁-SH) compound to form a disulfide bond (-SS-) (e.g.,



or



We can simplify matters considerably by referring to protein disulfide isomerase as PDI. So what happens is that when PDI is present in the same place with thiol-containing proteins, the result is that PDI will act, perhaps in conjunction with other compounds within the yeast cell, to provide disulfide-bonded

proteins. All you have to do is get the PDI in the same place as the thiol-containing protein. I think the invention basically involves an invitation to a scientist to conduct a "marriage ceremony" of the bridegroom PDI with the thiol-containing protein bride in a yeast-like church. Once the marriage takes place, the offspring are disulfide-bonded children.

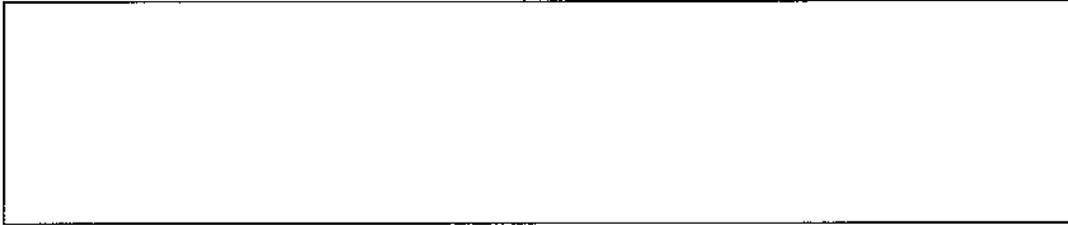
2. Explanation illustrated schematically

The invention is capable of being illustrated schematically after a brief explanation in words. Counsel representing biotechnology inventors before this board should become experts on the use of illustrating inventions schematically.

The invention involves a method of making a compound (i.e., a disulfide-bonded protein) in a medium which is a composition of matter (e.g., yeast containing genetically engineered genes). The object of the invention cannot be achieved with yeast in its natural state. Hence, it is essential that yeast in its natural state be changed by human intervention, or to use the words of our Supreme Court, be changed into a "human-made, genetically engineered"⁵ state.

We start with yeast in its natural state. Yeast is something you can see and will be illustrated as a simple box, as shown in Fig. 1.

⁵ Diamond v. Chakrabarty, 447 U.S. 303, 305, 100 S.Ct. 2203, 2205-6 (1980).



Yeast

Fig. 1

Actually, the box is a yeast cell.

Yeast is a living organism. So we can assume there are some "things" inside the yeast cell. There is no need to understand all the gory details of the nature of all the "things" inside a yeast cell. Suffice it to say that among other things one "thing" is "DNA." What is a DNA? Believe it or not, a DNA is simply a compound--a very big compound with lots of atoms. Initially we will say that the DNA looks like the "thing" shown in Fig. 2.



DNA

Fig. 2

So a yeast cell has DNA as shown in Fig. 3.



Yeast cell with DNA

Fig. 3

As previously mentioned, DNA is a very big compound with lots of atoms. The DNA can be said to be made up of various sections of atoms, some of which are "genes" as shown in Fig. 4.⁶

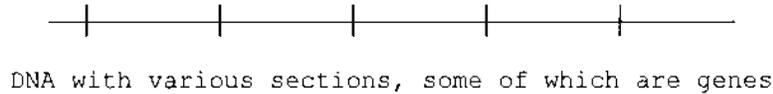


Fig. 4

We can label one section A as shown in Fig. 5.

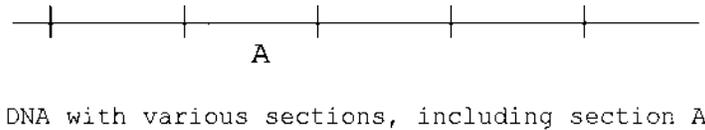


Fig. 5

So now what we have is a yeast cell having DNA which has at least section A as shown in Fig. 6.

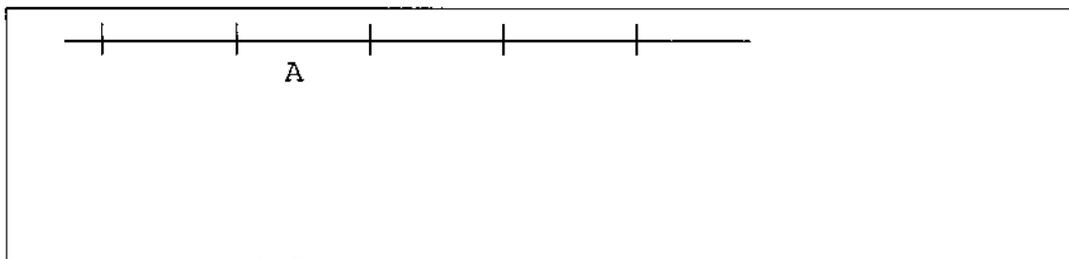


Fig. 6

It is probably a good idea at this point to note that we are still talking about yeast in its natural state. What is the big deal about section A? As it turns out, section A "encodes for" (again, biotechese for "makes") PDI. Hence, we now have a yeast

⁶ Compare Fig. 2-10 of Watson, "Recombinant DNA," Scientific American Books, page 25 (2d ed. 1992).

cell with DNA having section A all the while making PDI. For the time being, we will note that the various molecules of PDI simply are wandering around in the yeast cell as shown in Fig. 7.

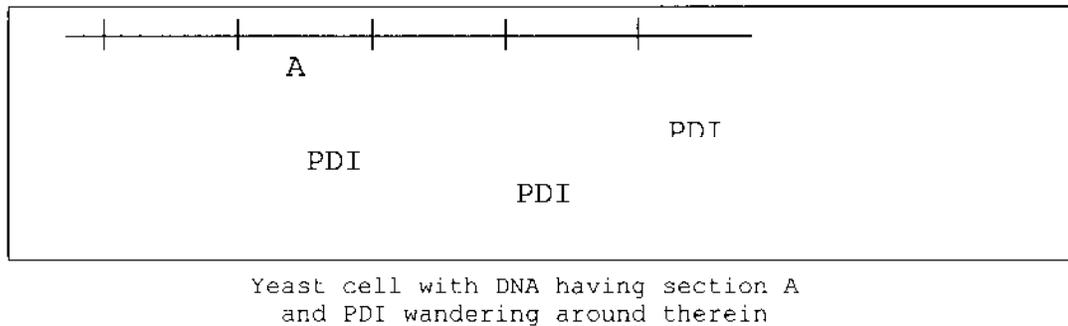


Fig. 7

Suppose you want to make a disulfide-bonded protein inside the yeast cell. What do you have to do? It depends. If the thiol-containing protein is one that the yeast makes on its own, then nothing need be done but allow the yeast to grow. The yeast will produce PDI on its own and it will act on any thiol-containing protein produced to convert the thiol-containing protein to disulfide-bonded protein. Suppose however that you want to use the now conventional, powerful tools of biotechnology to produce a disulfide-bonded protein which the yeast would not make naturally. What would you have to do? Basically, you genetically engineer the DNA in the yeast cell to insert therein a new section B as shown in Fig. 8.

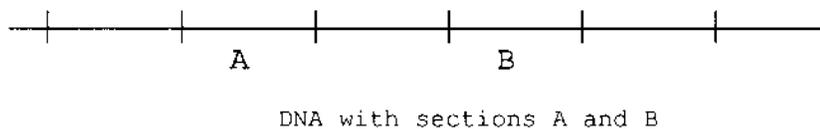


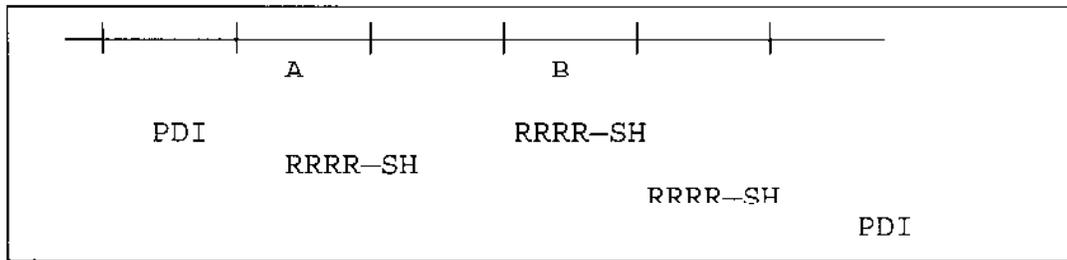
Fig. 8

Notice that adding section B makes the DNA an even bigger

compound, let's say a very, very big compound. Section B is not found in natural yeast, hence, human intervention has occurred. Yeast having DNA with section B genetically engineered therein is referred to by those with biotechese know-how as a yeast with a "recombinant gene"--maybe we could just say recombinant yeast. Adding section B may involve adding--to use the words of claim 2--a "recombinant expression cassette" ("cassette" is biotechese for "piece of material") or perhaps replacing one cassette for another in the DNA.⁷ If I understand the process correctly, adding a cassette is something like placing a cassette in your car radio to hear music except that the "bioteckees" would say the "recombinant" radio "expresses" or "encodes for" music. Harking back to claim 1 which mentions "recombinant genes," it should be mentioned that DNA "comprises" (well-known "patentese" which means "includes") genes. Genes are "small" parts of very big DNA compounds. Nevertheless, a gene can be right proud of the number of atoms which it owns. So, we can think of section B as a new "gene" which has been genetically engineered into the DNA of the yeast.

Of course, once you put section B in the DNA, RRRR-SH starts to be formed. So now we have a yeast cell with a DNA having sections A and B, with section A making PDI and section B making RRRR-SH, as shown in Fig. 9.

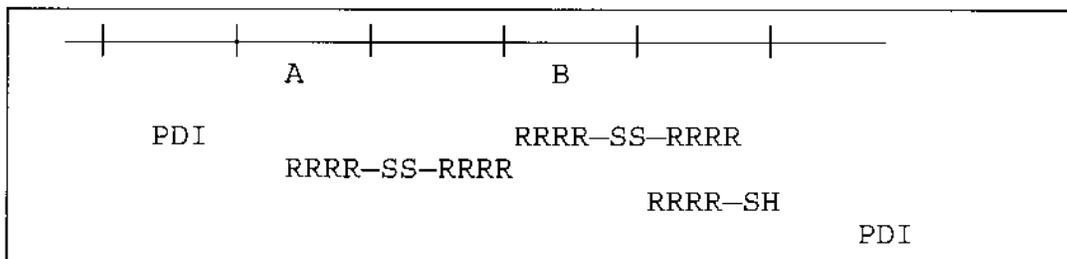
⁷ See Alberts, Molecular Biology of the Cell, Garland Publishing, Inc., page 572 (2d ed. 1989).



Yeast cell with DNA with sections A and B,
 section A making PDI and
 section B making RRRR-SH

Fig. 9

Since the PDI and RRRR-SH are now wandering around in the yeast cell, disulfide-bonded proteins are naturally made because when RRRR-SH finds itself in the presence of PDI, then the PDI catalyzes the formation of disulfide-bonded proteins RRRR-SS-RRRR. So now there are some disulfide-bonded proteins also wandering around inside the yeast cell, as shown in Fig. 10.



Yeast cell with DNA with sections A and B,
 section A making PDI
 section B making RRRR-SH and
 PDI catalyzing the reaction of RRRR-SH
 to make RRRR-SS-RRRR

Fig. 10

According to Toyoshima,⁸ a process similar to the process which I understand is going on in the yeast cell can take place in an E. coli cell (page 3, lines 18-28; page 7, lines 20-25).

⁸ European Patent Application 0 293 793, published December 7, 1988.

However, my limited background tells me there may be a big problem associated with using E. coli instead of yeast. It may be that to recover the desired product RRRR-SS-RRRR from E. coli, one has to destroy the E. coli cell and this would be a pain in the neck, at least the E. coli would think so because it has to be destroyed. Yeast, unlike E. coli, releases RRRR-SS-RRRR outside the cell (let's say the yeast cell secretes RRRR-SS-RRRR) where it can be collected without any need to destroy the yeast cell. Maybe that is why Toyoshima also describes the use of yeast (page 12, Example 6).

The invention involves "greed" in the sense that applicants seek to make the yeast work "harder"--specifically they seek to have the poor yeast "overexpress" (if "express" is biotechese for "makes" then "overexpress" must be biotechese for "makes more than normal"). Maybe "overexpress" is similar to having the previously mentioned "recombinant radio" turned up real loud. Nevertheless, the invention seeks to improve the lot of humankind by attempting to create and recover even more RRRR-SS-RRRR. To accomplish a greater recovery, it turns out that you have to insert yet another section into the DNA, say section C, to make "extra" PDI. The result of making "extra" PDI is more efficient formation of disulfide-bonded protein (RRRR-SS-RRRR). So now the DNA in the yeast has sections A, B and C--the latter two being genetically engineered into the DNA in the yeast. Applicants probably use the language "coexpressing" in claim 1 in an attempt to limit the scope of the claim to cover only those situations

where two sections, say sections B and C, "co-make" the thiol-containing protein and "extra" PDI.⁹ The new genetically engineered DNA now looks like the "thing" shown in Fig. 11.

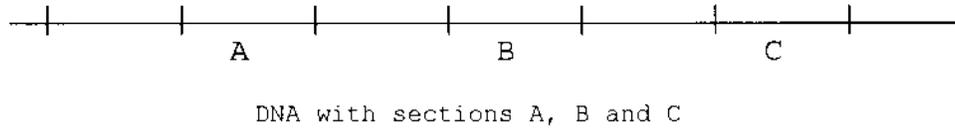


Fig. 11

Again note that the new DNA has now become a larger molecule than the DNA with sections A and B. In any event, the yeast cell now looks like Fig. 12.

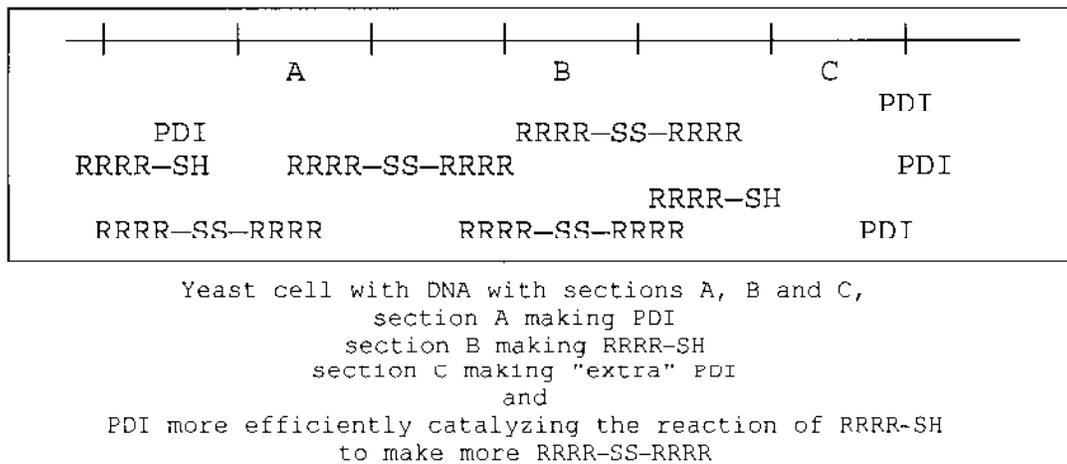
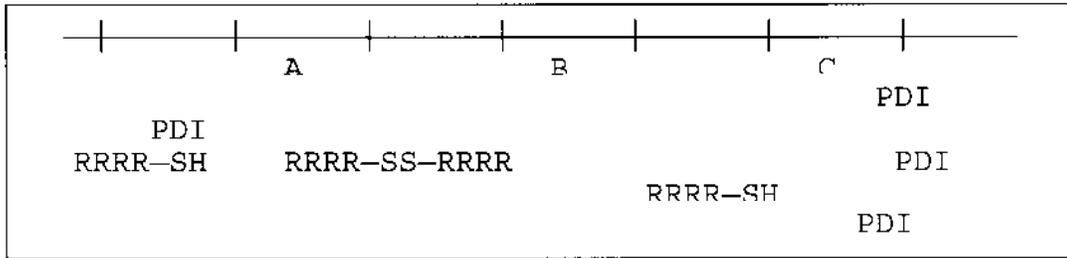


Fig. 12

As PDI is made by section A and "extra" PDI is made by C, more of the thiol-containing protein made by section B is processed within the yeast to make RRRR-SS-RRRR (i.e., disulfide-bonded protein) and some of the RRRR-SS-RRRR is secreted from the yeast cell where it can be recovered, as shown in Fig. 13.

⁹ As noted in the principal opinion, claim 1 as currently written may be read as encompassing a yeast containing DNA having sections A and B, but not C. In short, it is not clear exactly what the claim encompasses!



RRRR-SS-RRRR secreted outside yeast cell
 RRRR-SS-RRRR secreted outside yeast cell
 RRRR-SS-RRRR--secreted outside yeast cell

Yeast cell with DNA with sections A, B and C,
 section A making PDI
 section B making RRRR-SH
 section C making "extra" PDI
 PDI more efficiently catalyzing the reaction of RRRR-SH
 to make more RRRR-SS-RRRR
 and
 RRRR-SS-RRRR being secreted outside the cell
 where it can be recovered

Fig. 13

The RRRR-SS-RRRR illustrated outside of the yeast cell is the product which is recovered.

D. What I hope I have accomplished and a plea for help

My hope is that I have understood the invention. I am not at all sure that applicants are claiming the invention described in the specification. If I have misunderstood or misapprehended the invention, counsel can correct my misunderstanding or misapprehension should the application come before the board on a future occasion--hopefully using schematic diagrams (or perhaps correcting the schematic diagrams I have used herein).

I urge counsel to use their imaginations and freely rely on schematic illustrations to describe their inventions as well as

the subject matter described in the prior art. Educating the APJs of this board with respect to technical matters, particularly those in biotechnology, can help us administer justice in a cogent manner, while at the same time reducing what has become an unacceptably high backlog.¹⁰

FRED E. MCKELVEY,
Senior Administrative Patent Judge

¹⁰ Any reader of this opinion will be happy to know that writing this opinion did not get in the way of reducing the backlog. The bulk of the opinion was written on a Saturday night.

APPENDIX TO CONCURRING OPINION

Portions of the Commissioner's brief in
In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)

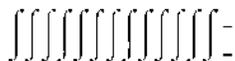
We agree that applicants correctly state the invention in biotechnology vocabulary as follows (Br7):

The invention is thus directed to chimeric genes [i.e., B—P's] encoding [an] insecticidally active Bacillus genes in Cyanobacteria [i.e., C]; vectors containing the genes and the transformed Cyanobacteria containing the genes.

The invention can be illustrated graphically with the following diagrams.

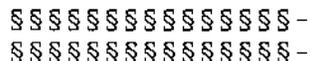
A bacterial code (B) can be illustrated as follows:

Bacterial Code (B)



A promotor (P) can be illustrated as follows:

Promoter (P)



The living cell (C) can be illustrated as follows:

Living Cell (C)



Diagrammatically (i.e., in "road map" fashion), the example in applicants' specification ("Exam."), the claimed invention ("Claims"), and the prior art can be illustrated as follows:

Exam.	Claims	Prior Art			
		Dzelzkalns	Sekar	Ganesan	Friedberg or Miller
C1 PL B1	C1-C9 PL B1-B2	C2 or E P B3	C10-C11 or E P B1	C11 or E P B2	C2 or E PL B3

1. The claimed invention is a "compound" which is hooked to a "device" to make a useful "combination."

2. The compound has two parts, a "P" part connected to a "B" part, i.e., (B—P).

3. The compound is then hooked to the device: "C."

4. The B—P—C "combination" happens to be a living organism.

Applicants' C—P—B differs from Dzelzkalns' C—P—B in that the claimed B is B1 or B2, whereas Dzelzkalns' B is a different B, i.e., a B3. Why would it have been obvious to replace Dzelzkalns' B3 with B1 or B2?

One skilled in the art would have known that a P—B1 (Sekar) or P—B2 (Ganesan) can be hooked to an E. One skilled in the art also would have known that a P—B3 can be hooked to a C2 or an E (Dzelzkalns). If

(1) a P—B1 (Sekar) or P—B2 (Ganesan) can be hooked to an E and

(2) a P—B3 (Dzelzkalns) can be hooked to either a C2 or and E,

then it would have been obvious to hook either a P—B1 or a P—B2 to a C2.

Applicants argue that one skilled in the art would not have hooked Sekar's P—B1 or Ganesan's P—B2 to Dzelzkalns' C2 because -- according to applicants -- one skilled in the art would not have known that a P—B hooked to a C10 or a C11 of Sekar or Ganesan would work when hooked to Dzelzkalns' C2. Applicants told the examiner that C2's are too different from the C10 and C11's. So what! Applicants' argument is irrelevant for the § 103 analysis, because it is the collective prior art teachings that P—B's can be hooked to either C2's or E's which makes it obvious to hook a P—B1 and a P—B2 to Dzelzkalns' C2.

Applicants further argue that there is no way to equate (1) a C2 with (2) a C10 and a C11 and/or an E. According to applicants, the C2 is an "algae" whereas the C10, C11, and the E are each a "bacteria." It turns out, however, that while C2 was once thought to be an algae, prior to applicants'

invention it came to be recognized as "blue-green bacteria."

Hence, C1-C9's, C10-C11's, and E are all bacteria.

Applicants still further argue that, based on the combined teachings of Dzelzkalns, Sekar and Ganesan, one would not know that the "P's" they describe would be suitable for use in hooking B's to both C2's and E's through P's. The examiner's answer to applicants' argument was Friedberg and Miller. Both show that applicants' P's (specifically PL's) work with both C2's and E's. Hence, one skilled in the art would have known what class of P's (actually PL's) to use when hooking Sekar's and Ganesan's P—B's to Dzelzkalns' C2.

Having disposed of the § 103 rejection, the examiner picked up on applicants' argument that the C2 of Dzelzkalns is so different from the C10 and C11's of Sekar and Ganesan that one could not have predicted that a P—B hooked on to the latter C's could be hooked on to a C2. The examiner, taking applicants at their word, asked "how do you know that the P—B1 or P—B2's of your invention can be hooked to each of C2 through C9's within the scope of your claim?" In short, the examiner asked applicants to "square" their "C2 is too different from C10 and C1" argument with the proposition that they broadly claim equally different C's, i.e., C1's through C9's. The examiner reasonably, in our opinion, wanted to know where applicants provided an enabling disclosure commensurate in scope with the breadth of their claims. Unsatisfied that

applicants' single example of C1—PL—B1 provided the requisite broad enabling disclosure, the examiner properly entered a rejection of the claims under 35 U.S.C. § 112, first paragraph.

We now proceed to a detailed technical discussion of why the position outlined above is correct.