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Impact of Recent Legal Developments on the Scope and Enforceability of Biotechnological Patent Claims

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IMPACT OF RECENT LEGAL DEVELOPMENTS ON THE SCOPE AND ENFORCEABILITY OF BIOTECHNOLOGICAL PATENT CLAIMS

*Herbert H. Jervis, Ph.D.**

Dr. Jervis: Can you hear me? I'll try to move around the stage as I talk. Patent attorneys never like to stay in one place too long. You understand, tougher to hit a moving target.

I'm sure your views on patent law differ. My experience with an audience like this is that your feelings run the gamut of emotions, usually from abject apathy to utter disdain. I don't know if I'll make any patent converts today, but I'll attempt to demystify the patent process for you by focusing on one aspect of patent law namely, the scope and enforceability of patent claims, particularly with reference to biotechological inventions.

It's appropriate that in this historical site that we talk a little bit about patents. In nearby Philadelphia, Samuel Hopkins was awarded the first U.S. patent in 1790 for an improved method of making pot ash. Contrary to popular belief, even biotech patents have had a long history of success in the patent office. In 1873, one Louis Pasteur was awarded U.S. Patent No. 141,072 for a yeast organism free from organic germs of contagion as an article of manufacture.

More recently, the U.S. Patent Office awarded its five millionth patent. (See: Fig. 1 - Page 86) The patent is directed to a microorganism into which genes have been transferred that permit the microbe to produce ethanol as a fermentation product. The microorganism, which you heard about earlier this morning, is *E. coli,* a very popular organism for bacterial genetic investigations. Presumably, it will be even more popular, at least with thirsty graduate students.

Before diving headlong into claim analysis, and since you've had a primer in biotech this morning, perhaps a primer in patent law is in order. Patent law stems from the U.S. Constitution. (See: Fig. 2 - Page 87).

Article I, Section 8, the patent clause, tells us that Congress has the power to promote science and the useful arts by granting to authors and inventors a time-limited exclusive right to their respective writings and discoveries.

Why so important? Why did the founding fathers believe that we needed patents? Well, you have to understand what a patent, a letters patent, is. Historically, there were two kinds of grants of rights. There were letters-closed and letters open. Letters-closed were rights in our English tradition, that were sealed by the Crown. They were secret. You had to break the seal in order to read what was in that document.

The other type of grant of right was a letters-open (i.e., Letters Patent). It was open for all to see, you didn't have to break the seal. Here I am holding a U.S. patent. It has the seal of the U.S. Government. Look what you can do. You can open it, you can read the information in the patent without breaking the seal. It's an open document.

It's a way that the government suggests is appropriate for information to be shared.

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The government says to the inventor, listen, we will give you a grant of right, if you tell the world about your invention. The alternative for the inventor is to keep the invention secret, telling no one about the invention. Does that progress the sciences and useful arts? No. However, by patenting, others can read about the invention and perhaps suggest an idea for an improvement invention.

So, I would suggest that patents are not necessarily evil things. What violence people do once they get a hold of one of these rights is something we'll talk about in a little bit.

Every Tuesday the U.S. Patent Office issues patents, and they are published in the Official Gazette. Now, this is interesting reading. If we have another winter like we did this year, it's something you can curl up with and await the thaw.

Let's take a look at what Congress' response was to the direction from the Constitution (See: Fig. 3- Page 88). A law was passed that provided that certain subject matter is, in fact, patentable. It states, whoever invents or discovers a new and useful process, machine, manufacture, composition of matter, or improvement thereof may obtain a patent.

Do you see the word "idea" in Figure 3 anywhere? No. Ideas aren't patentable. What is patentable are embodiments of those ideas, i.e., processes, machines and so on.

Without taking too much time, let's run through some examples taken from the Official Gazettes. Here are some machines (devices) that are patentable. Surgical saw blades (See: Fig. 4 - Page 89), laparoscopic cannulas (See: Fig. 5 - Page 90), balloon catheters (See: Fig. 6 - Page 91) are all patentable. Articles of manufacture are also patentable. Things like bowling ball inserts (See: Fig. 7 - Page 92) and tennis rackets (See: Fig. 8 - Page 93) are all patentable. This particular golf club is an interesting one (See: Fig. 9 - Page 94). If you read this patent, you'll see that this golf club is adapted to receive a shotgun shell. When the ball is struck and the shell is fired so that, according to the patent description, the ball goes 400-600 yards. Of course, the fatal flaw is that a slice also goes 400-600 yards.

Processes are patentable. (See: Fig. 10 - Page 95). This patent relates to a method of purifying a substance. Process claims are characterized by manipulative steps or acts (e.g. providing, separating, contacting, etc.)

Here are examples of compositions of matter, oxidoreductase preparations, that's an enzyme that was patented (See: Fig. 11 - Page 96). Here's a thrombolytic protein that's patentable, (See: Fig. 12 - Page 97). Even man-made cultures of microbes are considered to be compositions of matter (See: Fig. 13 - Page 98). The last part of the statute includes improvements of any of the foregoing classes of invention. Ready for this? Yes, you guessed it, it's a better mouse trap, that's patentable (See: Fig. 14 - Page 99).

And one last one before we move on which illustrates another interesting feature of patents, that being the patent literature actually is a rich source of information for cultural historians. That is to say, what you read in the Official Gazette are inventors' solutions to problems that were concerning the society at any given point in time.

So if one looks at the patent literature today and say, what is it that's bothering America, (because that's the grist for inventions), we find it is the time of HIV and safe sex. Accordingly, this is a U.S. patent relating to a force-sensitive sound-playing condom, (See: Fig. 15 - Page 100). It contains a pressure sensitive, electronic device on which you can record a message or play music. Of course, this went around our office like wildfire. People made suggestions of what music ought to be played. Some of our wives found out about it

and suggested perhaps the minute waltz would be appropriate.

On that note, let me offer just a brief commercial. If you look in your program, tomorrow we're going to talk about a number of different things in the workshops. I'll be hosting one and we will be talking about patenting in a relatively new area, the patenting receptor molecules and I invite everybody who would like to attend, to attend. The title I have chosen is Field of Screens - Patent it and they'll be Glum. (See: Fig. 16 - Page 101).

Okay, back to the topic. You didn't know how patent law could be so interesting and fun, right?

Member of the Audience: Is that all from that one volume?

Dr. Jervis: No, several but they come out every week .

Member of the Audience: That's a best seller.

Dr. Jervis: There have been lots of others, every patent attorney has a collection of his favorite patents. There was one I was going to bring but I couldn't find it. It is a device for the assisting in the birth of babies. What it is, essentially, is a barber chair that is spun real fast and a net.

A little more serious. Back to the law. What is this right that the government is granting you? (See: Fig. 17 - Page 102). The patent shall contain a grant for a term of 17 years to exclude others from making, using, and selling the invention.

The patent grant is a negative right, It's the right to *exclude* others from making, using and selling the invention. Think about that for a second. Nothing in the grant says that you have the right to practice your own invention. Rather, it gives you the right to exclude others from practicing your invention.

The analogy that's often used is the chair and the rocking chair. I make an invention called the chair and file for a patent claiming a chair comprising a back, a seat and four legs. The patent office examines my application and concludes new, useful and unobvious, nice invention, here, Herb, have a patent.

One of you in the audience reads my patent, says, gee, a chair, that's an interesting invention but I think I have an idea too. Suppose I put rockers on that chair, so now the chair rocks back and forth. A second patent application is filed claiming a chair comprising a back, seat, four legs and two rockers. The patent office looks at this application and concludes useful, new, unobvious, here's a patent on the rocking chair and it's your invention.

Question: Can the person who makes the invention of the rocking chair go into business selling rocking chairs? No, he can't, because what does he have to do before he builds a rocking chair? He has to build a chair, and I have the right under my patent to prevent others from making, using or selling something that comprises a back, a seat and four legs.

Now, I can't go into the rocking chair business by virtue of the second patent. He's got the right to exclude me from making, using or selling rocking chairs. So what do we do? We say, let's do a deal, I'll license you the right to build chairs if you'll give me the right to build rocking chairs. So that's how the patent system works in the sense of working with negative rights.

Back to biotech. A patent is organized into what is called the specification, that tells you how to make and use the invention, it provides a written description of the invention and it also tells you what is the best mode, that is, the best way the inventor knew how to practice his invention at the time he filed his application.

At the end of the document are a series of single sentences, that are called the claims. The claims are the metes-and-bounds of the invention. These are analogous to the metes-and-bounds of a deed of property. In this case it is a piece of intellectual property.

The object of the claims is to point out to the world what the inventor considers to be his piece of property. Normally, when you make the application, you draw the metes-and-bounds around your property fairly large, because you think you're entitled to an X quantum of property.

The Patent Office may look at such a claim and have a different view. And so there's a give and take, mostly give, that restricts the breadth, the metes-and-bounds, of your property.

What happens when I assert that claim against someone. I bring an action for infringement. The action is a tort and remedies include monetary damages and often as importantly injunctive relief. The court will go through a two-part analysis. The first thing they have to do is determine exactly what is the scope and meaning of the language of the claim. Once they've done that, then they compare the accused infringing device against that properly interpreted claim.

Let me give you a couple of examples of biotech claims. Before I do that let me put my mouse trap claim back up here (See: Fig. 14 - Page 99). The claim has three components that the courts will talk about. This first part, "the animal trap", is called the preamble, and it tells people what is the general area of the invention. The second component is this mystical word or phrase here, it's usually "comprising" or "consisting of". It's called a transition word or transition phrase and that will tell the reader whether the claim is so-called open or closed, and I'll explain the meaning of that to you in a minute. The third component following the transition word or phrase is called the body of the claim and it describes what are the metes-and-bounds of the invention.

Now all three parts can be used in interpretation of the claims, but the body is the business part of the claim that generally tells one what is the scope of the invention. Okay, the reason I had to do that first was because the first patent claim that I want to show you has an odd claim format. (See: Fig. 18 - Page 103).

See, this is a little bit different, because of how big the preamble is. I said the preamble was a simple statement of the general field of the invention. This particular claim form, for the patent attorneys in the audience, is called a Jeppson claim, named for the lawsuit in which the form was first developed.

These types of claims are used generally for improvement inventions. What you do in the preamble is to recite the old invention, and then after the transition phrase, you're then going to recite the new invention. So everything up to the preamble essentially is in the prior art, i.e., not novel. It's what was improved upon.

So if you read this claim, you find out that this is an assay claim, it's a way of doing an immunolgical test to determine the presence of an antigentic substance in a fluid. And what it involves is forming a tertiary complex between a first labelled antibody, an antigenic

substance and a second antibody. So those are the three pieces that form the complex.

The second antibody has to be bound to a solid carrier insoluble in the fluid in which you're doing the test. The presence of the antigenic substance is determined by measuring either one or two things, the amount of labelled antibody bound or the amount of unreacted labelled antibody. So that's the old immunoassay.

The transition phrase "the improvement which comprises", tells us what the improvement is going to be. Well, this improvement employs monoclonal antibodies. That's a different type of antibody than your routine serum antibodies, and they have to also have certain properties. Both the first and second antibodies have to have an affinity for the antigen of at least about 10 to the 8 liters per mole. So that is the subject matter of this invention.

Okay, this patent was the subject of a lawsuit between Hybritech Company and Abbott Labs because Abbott Labs was making, using and selling an immunometric assay that Hybritech thought was infringing that claim. What the Court had to do was interpret the language of that claim.

Now, we're talking non-biotech judges, a jury perhaps, lawyers who may not have backgrounds in biotechnology. You always have expert witnesses on both sides. You all know the definition of "expert", don't you? You have to parse the word. An "ex" is a has been, and a "spurt" is a drip under pressure.

First of all, what Abbott used in their assay were molecules called FAB fragments. Oh my God, not more language. A FAB, for the uninitiated, is really the front half of an antibody molecule. It's the business end of the antibody molecule and is involved in antigen binding.

So the first question that the Court had to answer was, did the claim include "fragments?" Do you see the terms FAB or fragments anywhere in the language of that claim — it says monoclonal antibodies. It doesn't say anything about fragments of monoclonal antibodies. So are fragments in or outside the scope?

When something like that happens, when the claim is not literally infringed, that is, you can't find the word "fragment" in the claim, infringement can still be found under the so called, doctrine of equivalents.

Now, the doctrine of equivalents as you might expect, is a subject on which entire courses are taught, but briefly the doctrine is designed to avoid what would be frauds on the patent. That is to say, somebody reading the patent and then making little, minor changes that just might be outside the literal language and then saying, oh, I don't infringe, I don't infringe.

But the courts can, by using their equitable powers, expand the scope of that claim a little bit to catch these sorts of infringers. As an equitable doctrine its, of course, subject to a certain amount of abuse.

What happened in this case was the court found through the evidence that, in fact, Abbott had literature that said, our antibody fragments are just as good as Hybritech's antibodies and they work just the same way, perform the same function, and give the same result. And guess what? That's the test the Supreme Court said that you need to satisfy in order to invoke the doctrine of equivalents. So not surprisingly, the Court said, yes, in this case, fragments of monoclonal antibodies are the same as antibodies.

The second issue dealt with the affinity limitation. Remember the patented monoclonals have to have an affinity of about 10 to the 8th liters/mole. The evidence revealed that Abbott's antibodies had an affinity of 4.6 to 4.8 times 10 to the 7th liters/mole, a little bit less. Of course, Abbott would say, a half order of magnitude less. The evidence showed that the test that was actually done to determine that affinity had a two or threefold error in it already. So the Court said, "about" means about, and 4.7×10^7 was close enough to 1×10^8. It infringed.

Lastly, the Abbott assay employed a mixture of antibodies, that is they used more than one type of monoclonal antibody. The question was, does "a first monoclonal antibody" mean more than one type of monoclonal antibody?

What the Court did this time, is to go back to the specification and ask what did the inventor contemplate? And right in the specification, it says, this invention contemplates using one or more antibodies. So, using all of the evidence, the patent itself, and the language of the claim, the Court came to a decision as to how to interpret the scope of that claim.

In this case, the word "about" was a critical feature, because it allowed the invention to then capture an affinity that was slightly outside the literal scope of the claim. So you say, whoa, boy, I'll put "about" in every claim I write. Well, you can try.

This is a claim from a famous patent infringement case between Amgen and Chugai over a molecule called erythropoietin (See: Fig. 19 - Page 104). Amgen won this case. They're now marketing erythropoietin (EPO). Chugai Pharmaceuticals, the licensee of another biotech company, called Genetics Institute (G.I.), were making EPO through a different method and obtained their own patent.

Here, look at this, here's the danger. This claims relates to a homogenous erythropoietin characterized as having a molecular weight of what? "about" 34,000 daltons. These guys read the case law, good attorneys, saw that "about" language in the Hybritech case and it worked, so we decided to give it a try. But look at this, the claim also calls for a specific activity of *at least about* 160,000 international units (I.U.) per nanogram.

Well, guess what, this was G.I.'s claim, and it failed. This claim was ruled invalid for two reasons. First of all, the court said that the specification, the written part of the application did not teach someone how to make erythropoietin of that level of activity.

The evidence disclosed that the highest level of activity that GI had reported to the government was in the range of 109,000 I.U. So where did the 160,000 figure come from? It turns out that G.I. did an experiment using high-pressure liquid chromatography where a fraction was recovered that had contained the EPO but also contained the contaminant, which I estimated was about half the area under the peak.

Well, the specific activity of EPO in that peak was 83,000 I.U. So what the G.I. did was say, well, listen, if it were pure, it would be twice that much, because we know half is the contaminant. So they doubled 83 and got "about" 160. So that's what they claimed.

That kind of evidence showed, at least in the Court's mind, that the patentee hadn't enabled someone of ordinary skill in the art to make homogeneous erythropoietin; of at least about 160,000 I.U., therefore, the claim was invalid.

The other issue was the "at least about" terminology. Okay, assuming that the 160 was a good number, G.I. showed 109,000 in their government filing. There was a reference, written by another scientist that showed 120,000. Chugai, G.I.'s own licensee, made EPO

and it was 138,000 I.U., and there was evidence that showed that Chugai worried that their EPO didn't fall within the scope of the G.I. claim.

And so all of that evidence, taken together, meant that in this case, nobody knew what "about" meant. Was is 120, was it 109, was it 160, was it 159? Because of all this other evidence it was deduced, the "about" language made that claim indefinite and rendered it invalid and the "at least" about was altogether too confusing for the Court to deal with.

However, the Court very quickly said, listen, that doesn't mean every time you use "about" it is wrong. In certain cases it is permissible, and I just showed you an example of that. So if you're going to use these kinds of terms, you need to give guidance as to what the term "about" refers. A good practice tip is to employ ranges. You could recite in the specification that the specific activity is at least about 125, preferable about 138, most preferably about 160, etc.

Well, I think that's about all the time I have I be glad to answer any questions.

Mr. Cooper: I'll tell you one thing, I never realized you patent attorneys were so much fun. Musical condoms? Take me away. At any rate, I have a confession to make. I did devise a tennis racquet with that shell in it. I'm having a little problem with tennis ball durability. Maybe we can talk about it.

FIGURE 1

5,000,000

ETHANOL PRODUCTION BY *ESCHERICHIA COLI* STRAINS CO-EXPRESSING ZYMOMONAS PDC AND ADH GENES

Lonnie O. Ingram, Gainesville, Fla.; Tyrrell Conway, Lincoln, Nebr., and Flavio Alterthum, Gainsville, Fla., assignors to University of Florida, Gainesville, Fla.

Continuation-in-part of Ser. No. 239,099, Aug. 31, 1988, abandoned. This application May 15, 1989, Ser. No. 352,062

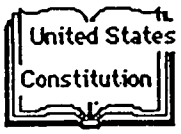
Int. Cl.[5] C12P *7/06*; CO7H *15/12*; C12N *15/00*

U.S. Cl. 435—161 7 Claims

1. An *Escherichia coli*, which has been transformed with *Zymomonas mobilis* genes coding for alcohol dehydrogenase and pyruvate decarboxylase wherein said genes are expressed at sufficient levels to confer upon said *Escherichia coli* transformant the ability to produce ethanol as a fermentation product.

FIGURE 2

Congress is empowered by the United States Constitution to enact legislation to protect the rights of inventors to their respective inventions.



Article 1, Section 8 of the Constitution provides Congress with the power -

> "To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

FIGURE 3

WHAT IS PATENTABLE SUBJECT MATTER?

35 U.S.C. §101

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

FIGURE 4

5,002,555

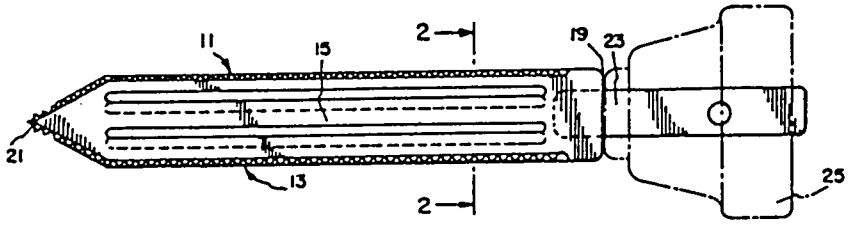
GALL-RESISTANT RIBBED SURGICAL SAW BLADE

Thomas D. Petersen, 9680 Alto Dr., La Mesa, Calif. 92041

Filed Feb. 10, 1989, Ser. No. 308,607

Int. Cl.[5] A61B *17/14*

U.S. Cl. 606—176 **8 Claims**



1. A surgical saw blade for use in conjunction with a slot having parallel guiding faces, comprising:

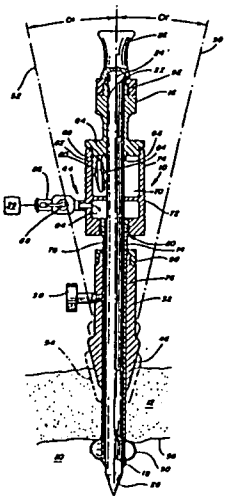
(a) an elongated body having first and second faces lying in substantially parallel planes and extending substantially the entire length of said elongated body, one of said first and second faces having at least one longitudinal rib protruding outwardly therefrom, the other of said first and second faces having at least two longitudinal ribs protruding outwardly therefrom and laterally staggered with respect to said at least one longitudinal rib;

(b) said blade having two sides defining the lateral extent of said first and second faces, at least one of said sides having a plurality of teeth thereon, respective adjacent pairs of said teeth defining a first thickness in a direction perpendicular to said substantially parallel planes;

(c) said first thickness being less than a second thickness defined by the outward extent of opposed said ribs whereby when said blade is inserted in a slot, parallel guiding faces thereof solely engage said ribs and said teeth are maintained spaced therefrom.

FIGURE 5

5,002,557
LAPAROSCOPIC CANNULA
Harrith M. Hasson, 2043 N. Sedgwick, Chicago, Ill. 60614
Filed Apr. 6, 1989, Ser. No. 334,452
Int. Cl.[5] A61M *37/00*
U.S. Cl. 606—191 21 Claims



1. A cannula for extension through tissue into a cavity, said cannula comprising:

a cylindrical sleeve defining a hollow passageway through which a surgical instrument can be directed,

said sleeve having (a) a proximal end to be manipulated by a user in directing the sleeve into its operative position through body tissue into a body cavity, (b) a distal end which projects into a cavity with the sleeve in its operative position, and (c) a cylindrical outer surface;

expandable means at the distal end of the sleeve for preventing withdrawal of the sleeve from a tissue with said expandable means in an expanded state,

said sleeve having a radial recess,

said expandable means being collapsible from its expanded state wherein it projects radially sufficiently to prevent passage through an incision to a collapsed state in which the expandable means projects radially not significantly further than the outer surface of the sleeve so as not to prevent passage of the distal sleeve end into and out of an incision in body tissue;

means for selectively placing said expandable means in the expanded and collapsed states;

a retaining collar having a tapered surface; and

cooperating means on the sleeve and collar for permitting movement of the collar relative to the sleeve towards the sleeve distal end whereby body tissue through which the sleeve is directed can be captured between the tapered collar surface and the expandable means to thereby maintain the sleeve in its operative position.

FIGURE 6

5,002,556

BALLOON CATHETER ASSEMBLY

Toshinobu Ishida, and Susumu Tanabe, both of Fuji, Japan, assignors to Terumo Kabushiki Kaisha, Tokyo, Japan

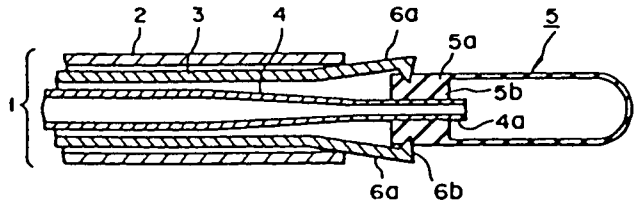
PCT No. PCT/JP87/00922, § 371 Date May 24, 1989, § 102(e) Date May 24, 1989, PCT Pub. No. WO88/03817, PCT Pub. Date Jun. 2, 1988

PCT Filed Nov. 27, 1987, Ser. No. 363,889

Claims priority, application Japan, Nov. 29, 1986, 61-284606; Nov. 29, 1986, 61-284607; Nov. 29, 1986, 61-284608

Int. Cl.[5] A61M *29/02*

U.S. Cl. 606—191 30 Claims



1. A balloon catheter assembly, comprising:

an expandable balloon having an opening in a proximal end portion thereof and including a marker made of an X-ray opaque substance;

an inner tube having a distal end portion which is removably inserted in said opening of said balloon;

an intermediate tube coaxially surrounding said inner tube with a space therebetween;

a chuck at a distal end of said intermediate tube, said chuck comprising a plurality of expandable and contractible holding portions; and

an outer tube surrounding said intermediate tube with a space therebetween;

said chuck being closed when pulled into said outer tube and pressed by said distal end of said outer tube to thereby hold said proximal end portion of said balloon, and said chuck being opened when pushed out of said distal end of said outer tube, to thereby release said proximal end portion of said balloon.

FIGURE 7

5,002,276

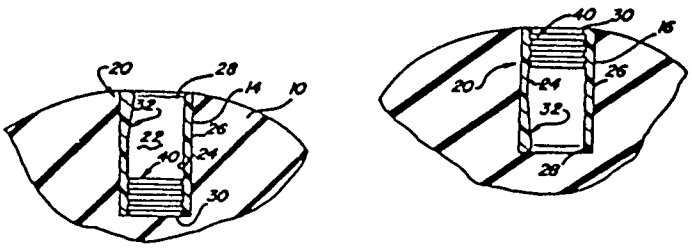
BOWLING BALL FINGER INSERT

David A. Bernhardt, Utica, Mich., assignor to Davalor Mold Corporation, Mount Clemens, Mich.

Filed Mar. 23, 1990, Ser. No. 498,009

Int. Cl.[5] A63B *43/02*

U.S. Cl. 273—63 A **26 Claims**



1. An insert for a finger hole in a bowling ball, comprising:

a tubular body having an outer wall surface adapted to be inserted into a finger hole of the bowling ball;

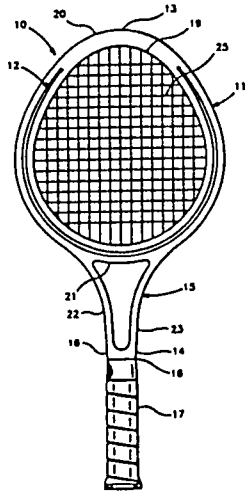
said body having an inner wall surface extending substantially coaxial to a central axis of said outer wall surface and defining first and second finger openings at opposite terminal ends of said body which are adapted to receive a fingertip therein;

ridge means extending along the periphery of said inner wall surface adjacent said second finger opening adapted for generating additional gripping force during delivery of the ball; and

a finger pad forming a thickened portion of said inner wall surface adjacent said first finger opening adapted for cushioning the fingertip and increasing contact area between the fingertip and the insert as compared to that provided by said ridge means.

FIGURE 8

5,002,278
RACKET
Juan C. Costa, 2564 Navarra Dr., #116, Carlsbad, Calif. 92008
Filed Nov. 13, 1989, Ser. No. 435,254
Int. Cl.[5] A63B *49/06*
U.S. Cl. 273—73 C **1 Claim**



1. A racket for striking a ball comprising:
a. an outer frame;
b. the outer frame being ovoid shaped;
c. an inner frame attached to the outer frame at a crown of the outer frame from between approximately a ten o'clock position on the outer frame to approximately a two o'-clock position on the outer frame;
d. the inner frame being ovoid shaped;
e. a smaller end of the ovoid shape of the inner frame being toward the crown of the outer frame;
f. a smaller end of the ovoid shape of the outer frame being the crown of the outer frame;
g. a shaft;
h. a bifurcated extension attached to a first end of the shaft and attached to the outer frame;
i. an interconnecting bridge on the bifurcated extension that attaches to a first side and to a second side of the bifurcated extension;
j. a handle attached to a second end of the shaft;
k. a plurality of first port means on the outer frame to facilitate stringing a ball engaging webbing onto the inner frame;
l. a plurality of second port means in the inner frame to facilitate stringing a ball engaging webbing onto the inner frame; and
m. a chamber means in the inner frame to facilitate stringing a ball engaging webbing onto the inner frame.

FIGURE 9

U.S. Patent Oct. 9, 1979 4,170,357

CLINIC I
Case 1
Page 1

3/182

FIG. 1

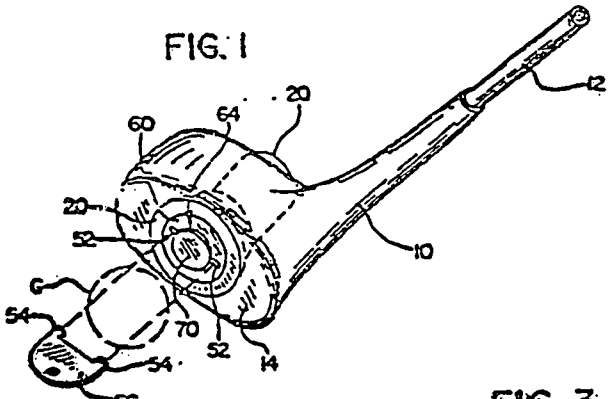
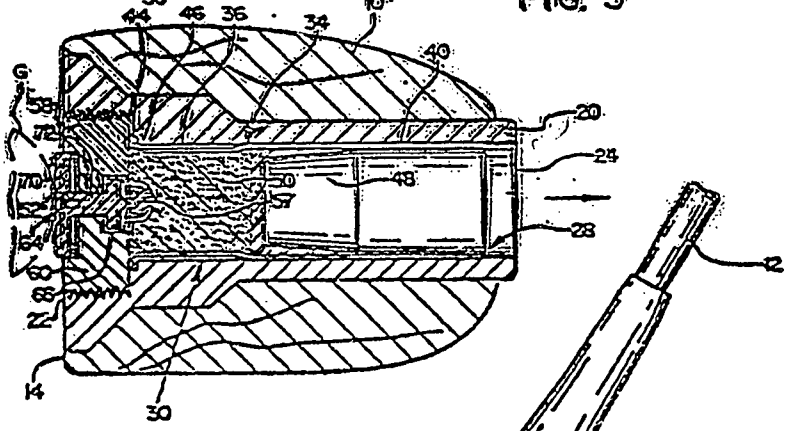


FIG. 3



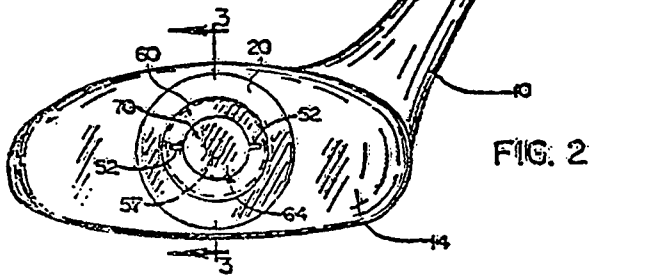


FIG. 2

FIGURE 10

5,003,047

METHOD FOR PURIFYING BIOLOGICALLY ACTIVE LIGATE

Martin L. Yarmish, Sharon, and William C. Olson, Brookline, both of Mass., assignors to Massachusetts Institute of Technology, Cambridge, Mass.

Filed Jan. 10, 1989, Ser. No. 295,442

Int. Cl.[5] CO7K *3/18, 3/20*

U.S. Cl. 530—413 12 Claims

1. A method for purifying a biologically active ligate, comprising the steps of:

(a) providing a ligand having a specific affinity for said ligate, said ligand being covalently bonded or adsorbed to a solid support,

(b) providing said ligate within a phase,

(c) contacting said solid support and said phase under conditions in which said ligand and ligate are contacted together to form a complex bonded to said solid support, said ligand and ligate being held together only by one or more non-covalent pressure-sensitive bonds,

(d) separating at least a portion of said phase from said solid support by washing said solid support, to provide a purified solid support comprising said complex bonded to said solid support,

(e) subjecting said purified solid support to a pressure of at least 300 atmospheres under conditions sufficient to cause release of said ligate from said solid support, said conditions not irreversibly causing the biological activity of said ligate to be significantly reduced,

(f) separating said ligate released from said complex from the immediate vicinity of said ligand, and

(g) recovering said ligate in its biologically active form.

FIGURE 11

5,002,886

OXIDOREDUCTASE AND THE PREPARATION THEREOF

Paul E. Gisby, Surbiton; Roger D. Newell, London, and Peter B. Park, Walton on Thames, all of England, assignors to British Gas PLC, London, England

Continuation-in-part of Ser. No. 840,763, Mar. 18, 1986, Pat. No. 4,810,641. This application Sep. 14, 1987, Ser. No. 95,866 Claims priority, application United Kingdom, Sep. 15, 1986, 8622714

The portion of the term of this patent subsequent to Mar. 7, 2006, has been disclaimed.

Int. Cl.[5] C12N *9/04*

S. Cl. 435—190 2 Claims

1. A polyol dehydrogenase obtained from a microorganism the genus Microbacterium which catalyzes the oxidation of lyols having as least one hydroxyl group on each of at least two adjacent carbon atoms to the corresponding aldehyde.

FIGURE 12

5,002,887

TRUNCATED THROMBOLYTIC PROTEINS

Glenn R. Larsen, Sudbury Mass., assignor to Genetics Institute, Inc., Cambridge, Mass.

Continuation-in-part of Ser. No. 825,104, Jan. 31, 1986, abandoned, which is a continuation-in-part of Ser. No. 853,781, Apr. 18, 1986, abandoned, which is a continuation-in-part of Ser. No. 861,699, May 9, 1986, abandoned. This application Jul. 3, 1986, Ser. No. 882,051

Int. Cl.^{5} C12N *9/48*

U.S. Cl. 435—212 3 Claims

1. A thrombolytic protein having a sequence selected from the group consisting of:

(i) the peptide sequence of FIG. 1 from Gly_{-3} to Pro_{527};

(ii) the peptide sequence of FIG. 1 from Ser_1 to Pro_{527}; and

(iii) the peptide sequence of either (i) or (ii) modified to contain Val instead of Met at position 245;

wherein Cys_6 through Ile_{86} are deleted and the N-linked glycosylation site at position 117-119 is modified such that Asn_{117} is replaced with Gln, said thromobolytic protein being glycosylated at at least one unmodified N-linked glycosylation site.

FIGURE 13

5,002,888

MUTANT MICROORGANISMS USEFUL FOR CLEAVAGE OF ORGANIC C-S BONDS

John J. Kilbane, II, Woodstock, Ill., assignor to Insitute of Gas Technology, Chicago, Ill.

Filed. Jan. 5, 1990, Ser. No. 461,265

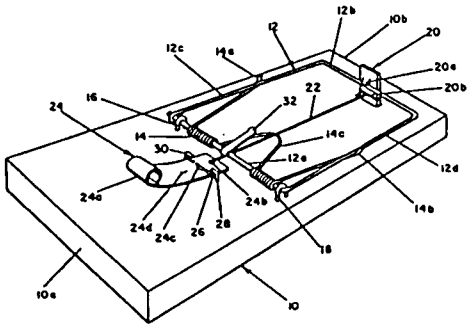
Int. Cl.[5] C12R *1/125, 1/07;* C12P *11/00*

U.S. Cl. 435—252.31 **7 Claims**

1. A biologically pure culture of mutant *Bacillus sphaericus* strain ATCC No. 53969.

FIGURE 14

5,001,857
ANIMAL TRAP
Howard J. McDaniel, and Billy McDaniel, both of 21 Donaldson Rd., Loving, N. Mex. 87256
Filed Aug. 14, 1989, Ser. No. 394,365
Int. Cl.[5] A01M *23/26, 23/24*
U.S. Cl. 43—81 20 Claims



1. An animal trap comprising:
a generally flat base comprising a forward end and a rear end;
a bail-type striker hinged to said base for relative swinging motion on said base between a cocked position at said rear end of said base and a sprung position at said forward end of said base;
spring means for driving said striker from said cocked position at said rear end of said base to said sprung position at said forward end of said base;
resilient latch means affixed to said rear end of said base and extending upwardly therefrom, said latch comprising means operable to engage and retain said striker in said cocked position, said latch means being resiliently disposed toward said rear end of said base so as to release said striker except when urged toward said forward end of said base;
a trigger plate comprising an integral downwardly protruding catch and integral fulcrum means, said trigger plate further comprising means for retaining a piece of bait placed thereon;
connecting means said latch means to said trigger plate; and
stop means affixed to said base, said stop means being engagable with said catch of said trigger plate, and said trigger plate, when engaged with said stop means, operating through said connecting means to urge said latch means toward a forward position retaining said striker in said cocked position;
whereby said trigger plate may be disengaged from said stop means upon said trigger plate being depressed downwardly, being lifted upwardly or being moved sideways, by an animal, so as to thereby release said latch means and allow said striker to be driven to said sprung position.

FIGURE 15

US005163447A

United States Patent [19]
Lyons

[11] Patent Number: 5,163,447
[45] Date of Patent: Nov. 17, 1992

[54] FORCE-SENSITIVE, SOUND-PLAYING CONDOM

[76] Inventor: Paul Lyons, 295 Elm St., Southbridge, Mass. 01550-3009

[21] Appl. No.: 728,607

[22] Filed: Jul. 11, 1991

[51] Int. Cl.[5] A61F 6/04
[52] U.S. Cl. 128/844; 128/883; 446/220
[58] Field of Search 128/842, 844, 885, 886, 128/883, 884; 604/347-353; 446/220-226, 404

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Primary Examiner—Robert A. Hafer
Assistant Examiner—David J. Kenealy
Attorney, Agent, or Firm—David Pressman

[57] ABSTRACT

A force-sensitive sound-playing condom comprising: a condom body (10) having a distal end and a proximal end, and a miniature force-sensitive sound-playing unit (14) attached to the condom at its proximal end. The proximal end of the condom is made in the form of a semirigid rim (12) having a lower part with an opening (16) coinciding with the cavity of the condom, and an upper part extending radially upwardly from the body of the condom and supporting the sound-playing unit (14). The latter contains a chip-controlled piezoelectric sound transducer which plays a melody or voiced message when during intercouse the contacts (28 and 30) of the sound-playing unit (14) are closed and the transducer is activated.

19 Claims, 1 Drawing Sheet

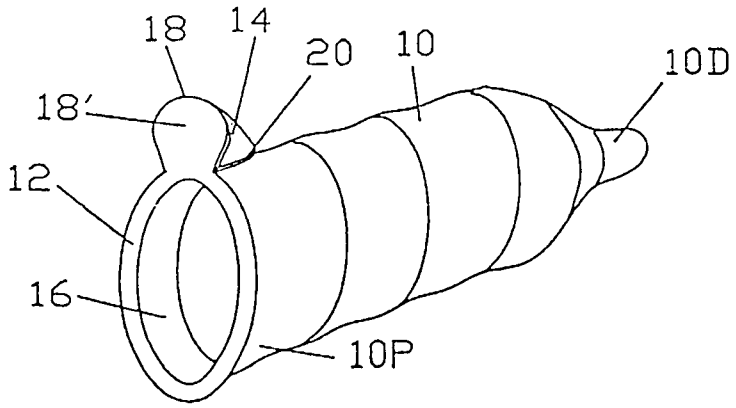


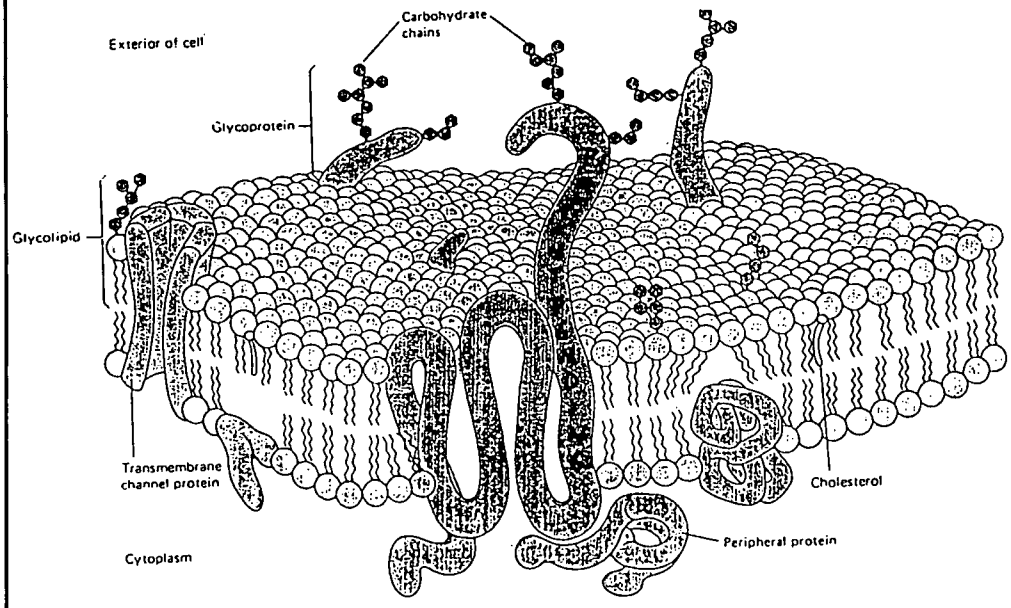
FIGURE 16

SMALL GROUP DISCUSSION

PATENTING RECEPTORS AND USES THEREOF
OR
FIELD OF SCREENS--PATENT IT AND THEY'LL BE GLUM!!

April 16, 1994
10-11 A.M.

Presented by:
Herb Jervis, Assistant Patent Counsel
SmithKline Beecham



Objectives: To discuss (a) the patentability of certain types of inventions in the field of receptor biology particularly with reference to screening protocols and technology, and (b) the types of patent claims which might be allowable in the U.S., Europe, and Japan.

FIGURE 17

THE PATENT ACT 35 UNITED STATES CODE

35 U.S.C. §154:

"Every patent shall contain... a grant to the patentee... for the term of seventeen years... of the right to exclude others from making, using, or selling the invention throughout the United States, referring to the specification for the particulars thereof."

FIGURE 18

In an immunometric assay to determine the presence or concentration of an antigenic substance in a sample of a fluid comprising forming a ternary complex of a first labelled antibody, said antigenic substance, and a second antibody said second antibody being bound to a solid carrier insoluble in said fluid wherein the presence of the antigenic substance in the samples is determined by measuring either the amount of labelled antibody bound to the solid carrier or the amount of unreacted labelled antibody,

the improvement *comprising*

employing monoclonal *antibodies* having an affinity for the antigenic substance of at least *about* 10^8 liters/mole for each of said labelled antibody and said antibody bound to a solid carrier.

Hybritech, Inc. v. Abbott Labs., 4 U.S.P.Q.2d 1001 (C.D. Cal. 1987), aff'd 849 F.2d 1446, 7 U.S.P.Q.2d 1191 (Fed. Cir. 1988).

FIGURE 19

Homogeneous erythropoietin characterized by a molecular weight of *about 34,000 daltons* on SDS-PAGE, movement as a *single* peak on reverse phase high pressure liquid chromatography and a *specific activity of at least about 160,000* IU per absorbance unit at 280 namometers.

Amgen, Inc. v. Chugai Pharmaceuticals Co., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991)