IN THE SUPREME COURT OF NEW ZEALAND SC 57/2009

BETWEEN **WYETH (NEW ZEALAND) LIMITED**
Appellant

AND **ANCARE NEW ZEALAND LIMITED**
First Respondent

AND **THE ENVIRONMENTAL RISK MANAGEMENT AUTHORITY**
Second Respondent

Hearing:	08 February 2010
Court:	Elias CJ Anderson J McGrath J Wilson J Blanchard J
Appearances:	B W F Brown QC and G Hazel for the Appellant J O Upton QC for the First Respondent D J Goddard QC and C Gregorash for the Second Respondent H M Aikman QC as the Amicus Curiae

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CIVIL APPEAL

MR BROWN QC:

10 If it pleases Your Honours, I appear with Mr Hazel for the appellant.

ELIAS CJ:

Thank you Mr Brown, Mr Hazel.

MR UPTON QC:

If Your Honours please, I appear for Amcare, and I have an application to make as regards my position at some convenient time.

MR GODDARD QC:

May it please the Court, I appear with Mr Gregorash for the second respondent, the Authority.

ELIAS CJ:

Thank you Mr Goddard, Mr Gregorash.

MS AIKMAN QC:

And, Your Honours, I appear as Amicus for the Court.

ELIAS CJ:

Thank you Ms Aikman. Well, it is convenient to hear your application.

MR UPTON QC:

Well, Your Honours, it's simply that my client takes a neutral stance, abides the decision of the Court. My company is in liquidation, and the position has been noted, so in those circumstances, I seek leave to withdraw.

ELIAS CJ:

Granted, Mr Upton. Thank you for attending today. Mr Brown?

MR BROWN QC:

May it please Your Honours, naturally I don't seek to submit any new material, but my speech notes are written, and if at any time, any member of the Court wanted them as a roadmap, I'm very happy to provide them. Your Honours, the starting point, of course, is the statute. Before I come to the approved question and our submission, a little bit about the structure of the Act and the subject matter of it. The first point, of course, is the real subject matter, the hazardous substance, and the definition of "substance", both in section 2

subsection 1, and the definition of “organism” and, similarly, “new organism”. New organism has its own provision in section 2(A)(1). And then I would draw attention to the important provisions in part 2. This part is under the heading “Purpose of the Act”. And there are four sections that I draw attention to, as Wild J noted, as, indeed, the Court of Appeal noted. Section 4, that is the purpose of the Act, protecting the environment and the health and safety of people in communities by preventing and managing adverse effects of both hazardous substances and new organisms. Then Section 5, the principles relevant to the purpose of the Act, which list a series of a number of principles. I draw attention to the second, the maintenance and enhancement of the capacity of people and their communities to provide for their own economic, social and cultural wellbeing. Then Section 6, matters relevant to the purpose of the Act, which highlights, among other things, the intrinsic value of ecosystems in public health. And then 7, the precautionary approach. All of which, in our submission at paragraph 17, we submit, serve to emphasise the focus in the Act on the protection of the environment, and the health and safety of New Zealanders. And then, as noted in paragraph 2 of our submissions, the structure of the Act, how does it seek to achieve that? It does that by a statutory technique, a prohibition on all importation or manufacture of hazardous substances, and all importation, development, field testing, or release of new organisms otherwise approved under the Act. To do that without approval is an offence, and there are significant penalty provisions. And that structure, that technique of prohibiting subject to approval, leads to the significant list of different types of applications for approval, and I have collected them at paragraph 22 of our submission. The first bullet point is the one that happens to be the item, subject of the application that led to this litigation, importing or manufacturing hazardous substance otherwise in containment. That’s section 28. Then there’s section 31, importing into containment or manufacturing in containment any hazardous substance. There’s section 34, importing for release, or to release from containment any new organism. And then section 38(A), one of the introduced provisions, a conditional approval to import for release or to release from containment any organism with controls. And then section 40, importing into containment, or developing in containment, a field test any new

organism. And then the emergency provisions in section 47 and section 49(b). And several, but not all of those, are required to be publically notified. Now, the particular application that led to this litigation was an application under section 28. And if I could take you to the second volume, just to familiarise yourself with the application, it's under tab 8. It's an ERMA form, and on page 87, the first page under tab 8, you'll see "Application for approval to import or manufacture any hazardous substance for release". So this is not a containment-type application. And you'll see the name of the substance, MEP 600, that's the code name that is the focus of our appeal and the approved ground of appeal. And then you'll see the application code, it's hand-written at this point, in the box there, HSR06071. That's the application code that that application has for its life. Throughout the application process, it has the public persona of MEP 600, and in that regard, if I can ask you, it's the only time I'll take you to the affidavit, it's in the third volume under page 17. This was an affidavit that was submitted quite late in the piece in the High Court. It's on page 382 of tab 17 of volume 3. It was an affidavit – yes, it's dated the 14th of May, so it was tendered only two days before the hearing before Wild J. And the reason, it was to give details about various matters. The reason I'm referring to it is paragraph 8 on page 384, because this was how ERMA portrayed this number, it's at MEP 600, it's a code name created and used by the applicant to identify the substance that is the subject of the application. Use of a code name is a practical method of uniquely identifying the single substance for which an approval is being sought, and is a method commonly used in applications under section 28. The substance identified as MEP 600 is, in fact, a mixture of more than one component. The code name is used to uniquely identify the substance on a register of all applications maintained by ERMA New Zealand. The substance, once approved by ERMA New Zealand, may be marketed under trade names that are different to this code name. Now, I'm not going to go through the process, that's not really part of the approved ground of the appeal, but I just drawn attention to a couple of documents that cite MEP 600. There was the public notification, which we note in our paragraph 12 –

ELIAS CJ:

Before you go on to that, what's the section for public notification of applications under section 28?

BLANCHARD J:

53(1)(a).

MR BROWN QC:

Yes, as Blanchard J has said, 53(1)(a). Those applications requiring to be publically notified, and then in subsection 3, the manner of the public notice, and then 53(A), there is a special section that is taking into account cost considerations, as well, as to the method. 53(1)(a) is the requirement to publically notify section 28 applications.

ELIAS CJ:

Yes, I see.

MR BROWN QC:

But I was just drawing attention to 53(3), which talks about the content of the notice. And then there is also section 53(A), which is a section which also addresses the method of public notification. The call for submissions may be of interest. That's under tab 11 in volume 2 at page 111. It's an interesting document in a practical sense, in it shows that the varieties of degrees of notice that are given by different applicants. Some of them have code names. Here, MEP 600 is the last one on that page, but there are a number of others giving a greater or lesser degree of information. We know, for example, the one immediately above MEP 600 identifies the active ingredients, metalaxyl and mancozeb. But we know from the material helpfully put before this Court by my learned friend for ERMA that, in relation to section 28 applications, we don't have them for all the others, but 28, it would appear to be approximately 60 percent have had code names used in the period of the last four years. So that's the rough balance.

MCGRATH J:

Are the code names devised by the applicants?

MR BROWN QC:

Yes, yes.

MCGRATH J:

There's no attempt to try and regulate that?

MR BROWN QC:

No. There is ERMA's application code, there is ERMA's approval code, and then there is a code name, if given. And as it happens, I'm not aware of any code name that is not an alphanumeric combination. As I've noted, Robertson J in the Court of Appeal said "Mickey Mouse could be used". But in fact, all the ones seem to be a combination of letters and numbers. It looks like, to the untutored observer, MEP 600 may be thought to indicate something to someone. But in my submission, it's no different from ABC 123, or anything else. And we'll come to some of those in a moment. The application was approved subject to controls, and it would probably be useful just to see that as well. That's under tab 14 at page 189. This is the actual decision approving the application to import or manufacture MEP 600. It's a standard form of document. It starts off with a summary of the decision, and we'll be coming back to this document, because it lists the controls. You'll see at page 199, there is appendix 1 to this decision, which are the controls for MEP 600. But the decision itself is the document that gives authority, and has its own number. If you look in the middle of that page, summary of decision. 1.1 says, "Application to import or release MEP 600 is approved with controls". Then it says in 1.2, "The substance has been given the following unique identifier for the ERMA New Zealand Hazardous Substances Register", MEP 600. And then it gives the ERMA New Zealand approval code, which we see there is HSR007663. Your Honours might be wondering why, at the top of the page, it says "Amended under section 67(a)". The reason for that is that the first decision that was released erroneously used the same number for the approval code as the application code, and that's not a

practice that ERMA follows. So in order to have a different number of application than approval, the decision was re-released, and that is the amendment that is reflected in the amendment under section 67(a) on the 1st of November.

ELIAS CJ:

What is the code that's used for the register?

MR BROWN QC:

MEP 600.

ELIAS CJ:

The approval code or the application code? If it's not susceptible to an easy answer, don't worry.

MR BROWN QC:

Well, they're both, Your Honours. If you look at the very last page of volume 3, you'll see what is a register search by computer, which is page 389, which has MEP 600 at the top. And then about halfway down, you'll see the application code listed, and then right at the bottom of the page, you'll see the approval code listed. The reason I hesitated in that response is that neither of those things are required by section 20 relating to the register. So your question to me –

MCGRATH J:

But the register is only of applications, isn't it?

MR BROWN QC:

I'm going to come, Your Honour, in a moment to what that is. It's a register of applications, all applications, but then it records their approval or their fate and their controls and the like, yes. So it's applications, but it's intended to be a register that records –

MCGRATH J:

What's happened to them.

MR BROWN QC:

Yes.

MCGRATH J:

I would like to see that as we go through, because I did notice that section 20 refers to keeping a register of applications only.

MR BROWN QC:

Yes, that's right. Sorry, what would you like to see?

MCGRATH J:

You're going to show us later that the basis on which what happened to applications, the Act provides that that's to be specified in the register? Is that what you're saying?

MR BROWN QC:

Yes, that's right, section 20. I thought of starting with section 20, but I thought it was helpful to have the, how the Act works briefly before we got to that point.

ELIAS CJ:

Why – I know that this is the question that has been posed for the Court, but why do you start with section 20 rather than section 28?

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MR BROWN:

Because section 20 is the section that requires there to be a public register available. What – the source of the material that will appear in the register will be various items of information that are in applications made under section 28 and all the other types of sections as well because, as we'll come to see, the

provisions that are listed in section 20 have matters that derive from other sections than 28.

ELIAS CJ:

But in this appeal, you're not complaining as you did originally about the lack of information to enable your client to participate in the application hearing which would turn on the application of section 28?

MR BROWN QC:

No, the approved question relates solely to what the Act requires the register to state. If we could just look at that for a moment because it is –

ELIAS CJ:

No, I just want to make it absolutely clear that that is all we're concerned about on your appeal?

MR BROWN QC:

That's right. Although, I have to say that if the register requires, as we argue it does, requires a sufficient description of the substance or new organism and that is on the register, the practical effect of that will be that the hearing of any applications, that will be disclosed matter. It would be a nonsense for the register to say what the – a description of the substance or organism on the one hand and the public hearing not to have that information available to it and you just go and look at the register. So, we did argue that the complaint was directed both at the register and also the way in which the hearing is conducted because what, what – the argue for Ancare and it would be said I think, supported by ERMA and now the amicus is driven from the application procedure and what is said to be the entitlement of ERMA to treat various categories of matter as confidential and they go so far as to treat the identity of the substance as confidential. We say, that can't be so, it makes a nonsense of the process but the register of applications requires you to sufficiently describe it. That is why the code name is used on the register, it's to avoid the problem of having to reveal the active ingredients in the course of the public hearing process and I'm going to come to the difference between

this is highlighted by the proposition they make which I say is a red herring, that well this is a temporary state of confidentiality because before long there will be labels out there telling it and I say well, that's all very well but you've got labels out there saying what it is and you've got a register MEP 600.

ANDERSON J:

What if the register had the trade name of the substance? It rather seemed to me that the purpose of the register might be so people who see something being sloshed round a paddock can check out whether it's permitted or whether it's consistent with any controls imposed.

MR BROWN QC:

Yes, that would go some way. Although, in my submission, the trade name of the product, let's say, you know, sort of, Glow Worm, would not be, would not meet the requirement in section 21B of a sufficient description of the substance or organism to uniquely identify it. It may identify it but it wouldn't actually describe anything about the substance or the organism.

ANDERSON J:

Not but it would permit a member of the public to go the register –

MR BROWN QC:

Yes it would.

ANDERSON J:

– and see whether it's consistent with controls imposed or whether it's even permitted.

MR BROWN QC:

That's right and this is the – well, I agree with that although the bizarre point I'm saying, is that if you've got something out there with a label on it that says –

ANDERSON J:

I understand, okay.

MR BROWN QC:

– this is Glow Worm but there's a register, you go to the register it won't say Glow Worm, it says MEP 600.

ANDERSON J:

Yes, I take that point but it may mean that the requirements of section 20 can be met without disclosing the chemical structure of the substance –

MR BROWN QC:

Yes –

ANDERSON J:

– so long as it's recognisable to the public who really have the function of policing and supervising.

MR BROWN QC:

– and it's critical on that point however, that when you talk about without disclosing the, sort of the chemical structure, this is not an exercise to try and find out some secret that would otherwise be known. We're not talking about – when you come to something like a chemical, there will be the molecule and if it's original, it will be the subject of a patent, it will be going for 20 years protection. We're not talking here about then at the other end trying to find the formulation, or what excipients. All that we're talking about is a sufficient description of the hazardous substance. Now that may be the whole or it may be, in some instances, an ingredient or in this case two ingredients because when we come to look at the controls, the controls require this labelling to specify ingredients A and C and I don't know what they are but they are obviously the matters of concern to ERMA and I'm going to come to the register and how these things are displayed. When you say the chemical structure is important, we differentiate between, as it were, sort of patented material, formulation material, dosage material, we're simply here driving for

all that the register requires, a sufficient description of the hazardous substance.

ANDERSON J:

I just wonder whether the correct approach is to ascertain what the purpose the register is. It can't be a notification process because there's a separate notification process. It's really a logging process so the members of the public can check whether something is approved and if so, on what terms and therefore there must be some correlation between what the public, or the monitors whoever they are, can observe and what they can check against and they won't be seeing MEP 600 on the sides of the cans presumably?

MR BROWN QC:

I don't think so.

ANDERSON J:

So that the supervisory process breaks down unless there is some correlation between the use of the product if it's approved and the way it's logged through the approval process.

MR BROWN QC:

Well, as you will see, there is quite a void between my learned friends and myself about the purpose of the register. They seek to downplay or diminish the role of the register, although there's an interesting point that my learned friend the Amicus, we had a debate before Your Honours came in as to what's the correct pronunciation, I'm gone with Amicus, I think that's the collective view, Dr Barton wasn't available for – ah, the, she makes the point in her submissions, well the register isn't the first port of call in an emergency and I say probably not, might be the second or perhaps the third. My learned friend Mr Goddard's submission says the register is the initial point of looking for something about the substance, so there's a dichotomy there. We say the register probably serves a number of purposes but it certainly has a capacity for an emergency situation. It also has a capacity for someone who wants to find out if something actually is approved. You see, things only get approved

once. If you go to section 28, section 28(1) begins by saying, "Unless an approval under section 28A or section 29 applies to the importation or manufacture of the substance, every person intending to import or manufacture a hazardous substance otherwise than shall apply." Well, the very first thing if I've got a hazardous substance that I think might have been the subject of an approval, I'll go to the register to check and MEP 600 isn't going to tell me anything about that. I know what's in my product, I perhaps know the code name I would use if I was going to play the code name game but my looking at a register that has a whole lot of alphameric codes for the sufficient description of the substance, I won't find anything out. So there's emergency, there's someone who's a, not necessarily a competitor but someone who is thinking of getting something and the my learned friend Mr Goddard say well, we're very co-operative, you could ring up and ask us. Well I suppose you could, although I think some people might say well I'll use the register, that's what they're for.

ELIAS CJ:

What's the link between the approval process and the register because it does seem to me that what's being put to you by Justice Anderson is quite compelling but the register may serve a much more limited purpose quite adequately by notification which identifies what people are using but it maybe different where you applying to use a hazardous substance and you have a system of approval. Under section 28, the information that's required in order to allow people to participate in that approval process maybe different. So, what is the – I maybe overlooking something in the structure of the Act in terms of the linkage between section 28 approvals and section 20?

MR BROWN QC:

No, no, you're not and my learned friends would, you know, if the approved ground permitted them, would spend their time I think in a sort of a Official Information Act type argument about the application process. That's under part 5, the register is in part 4 and I think it probably is helpful to go directly to it, I wasn't meaning to go –

ELIAS CJ:

Is there a link?

McGRATH J:

I'm certainly, this is really what –

MR BROWN QC:

Yes, yes –

McGRATH J:

– I'm certainly looking for the indications in the statute that you have to have on the register, the approvals and I think that that's the question –

MR BROWN QC:

– let's go to section 20. Did I –

McGRATH J:

– that Justice Anderson has highlighted as well.

MR BROWN QC:

I made a request for Your Honours to have the Act. I think I was told that you have it online but do you have the Act in front of you?

ELIAS CJ:

I've got it here.

MR BROWN QC:

Section 20 is the "Obligation to prepare and maintain a register. The Authority shall keep a register of all applications made to the Authority." So, it's not just section 28. "The register shall specify the name and address of the applicant" and this is the phrase then that we're agitating about, "A sufficient description of the substance or organism to uniquely identify that substance or organism." Well you see immediately of course that because it's organisms it's not just limited to substances which is section 28. Then you've got the, "The purpose

of the application." Now, a point I make later in my submissions, the purpose of the application is not something that is actually listed in section 28 but purpose interestingly, is in section 31. If you look at the requirements in section 31(2) of what the application there is required to disclose, again you've got, "(a) Identification of the substance for which approval is sought" because that's throughout, all applications require identification, either through the use of the word identification or the verb identify but "(b) The purpose for which approval is sought." So section 31(2)(a) –

ELIAS CJ:

Sorry, the substance must be a reference to the hazardous substance, mustn't it?

MR BROWN QC:

Yes, it is because this section is only dealing with substances.

ELIAS CJ:

Yes.

MR BROWN QC:

There are discreet sections dealing with new organisms.

ELIAS CJ:

But it's not the compound insofar as the compound, the product, contains non-hazardous substances. That's not what is envisaged here, is it?

MR BROWN QC:

No, no, I don't believe it is. There's a degree of fuzziness I think, around what people understand by the hazardous substance but the rationale of the Act must be to disclose what it is – if you look at, I jumped over hazardous substance but hazardous substance on page 12 of the printout I've got of the Act talks about substances, "With one or more of the following intrinsic properties, explosiveness, flammability, a capacity to oxidise, corrosiveness,

toxicity" and that's defined as being potentially damaging to humans and eco-toxicity which is potentially damaging to other organisms.

ELIAS CJ:

It was only eco-toxicity here, wasn't it –

MR BROWN QC:

Yes.

ELIAS CJ:

– did I read that somewhere?

MR BROWN QC:

Yes, it is, it, this sort of stuff gets into water, it's –

BLANCHARD J:

It suppose that there's no need specifically to mention purpose in relation to section 28 because section 28(1) actually does state the purpose which is either importation or manufacture?

MR BROWN QC:

Yes.

BLANCHARD J:

So there's no real inconsistency there?

MR BROWN QC:

Oh no, no, no inconsistency and can I just correct myself, I heard from my learned friend Mr Goddard from behind, I think this is both eco-toxic and toxic.

ELIAS CJ:

Oh I see, yes, thank you.

MR BROWN QC:

Yes, grateful to him. No, I'm not suggesting inconsistency Your Honour, I'm just saying that whereas the Court of Appeal's judgment, I suppose naturally enough tends to focus on 20 and 28, in fact we're talking about a register that covers all the parameters. Perhaps I could make my point a little better by taking you to section –

ELIAS CJ:

Actually I see that substance is defined and so what I've said is – what I suggested about identifying the hazardous substance only, is probably not correct because it includes the whole thing, the combination?

MR BROWN QC:

Well, in paragraph (d) of it?

ELIAS CJ:

Yes but, well, some of the others as well perhaps.

MR BROWN QC:

"Any manufactured article containing or incorporating any hazardous substance" so it brings it round that –

ELIAS CJ:

But that's with explosive properties but the others – it seemed to extend to everything in a compound.

MR BROWN QC:

Well, what the register, in my submission, what the register is designed to disclose is a description of the substance, that that must mean the hazardous substance because each of the applications that has been talked about is either a hazardous substance or a new organism –

ELIAS CJ:

Well, it has to contain a hazardous substance but it's not just the hazardous substance because of the definition of substance.

MR BROWN QC:

That my well be the case but what I want to come on and make is the point of controls and we haven't touched on controls yet and they're very important. They can identify the particular ingredients wherein the danger lies and they do that, we'll see in this application and they are on the register by virtue of (e) and (f), that is the controls. I'm having to jump ahead of myself here but these are the controls attached to the approval, so that the combined effect of the register will be a sufficient description of the substance or organism, whatever one views that as being but I don't, in my submission, it would be unlikely to be a mere trade name with respect because a trade name could be pitched in such a way that it didn't really take you much further than a code name but then the controls, if there is something or if you've got a situation as you could have, where there are two toxic substances or two substances that in combination cause toxicity, not a common event but possible, then the controls system will also bring that to the attention of the public because it's listed on the register.

ELIAS CJ:

Well, let's say for example you have to wear gloves and masks and that would be an indication that it's toxic, presumably?

MR BROWN QC:

Yes, yes, well it's more, a little more detailed than that in terms of the requirement, to be able to identify it categorically within two seconds and 10 seconds as the case may be and if I may, I'll take you to those specific controls –

ELIAS CJ:

Yes, sure. Just while you're on section 20 though, the unique identification and I know that there's quite a lot in your submissions and in the submissions

of the others, about comparing unique identification with section 28, what was that, the –

MR BROWN QC:

Unequivocal identification.

ELIAS CJ:

Unequivocally, yes but unique identification seems, at least at first sight, to carry the requirement that there can't be confusion between one substance and another which is not necessarily the same thing as, "An unequivocal identification of the substance and its properties"?

MR BROWN QC:

I agree with that but –

ELIAS CJ:

So it is a sort of a registration driven end that's looked at?

MR BROWN QC:

Yes, although the – and there has been a lot of focus on unequivocal, probably because there's been a focus on 28 but if I could ask you to note this, that section 28(2) is the only one of the several sections that requires identification of substance or new organism, as the case may be, that has a qualifier like that, unequivocal and it's also the only provision that couples properties with it. Now, I don't know whether it's helpful or not that they did that but they have an unequivocal identification of the substance and its properties, whereas if you come to section 31(2)(a), you get identification of the substance for which approval is sought. If you come to 31(2)(c), you get identification of the organism. If you come to 38A(2)(c), you get identification of the organism and there's a danger, in my submission, in focusing on the register in a section 28 context because the register is for all applications. It's the happenstance that it's section 28 that brings us before you, but the register is for all identification or unique identifier in (2)(b) of section 20 is for all these matters that are all these types of applications.

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ELIAS CJ:

But is it not possible that there are layers of requirement that are being imposed here? There must be an unequivocal identification of the substance and its properties in the application. That must be so, because otherwise ERMA could not assess it. But for the purposes of the register, it's enough that this substance can't be confused with another, perhaps. But what is necessary is some linkage between the section 28(2) requirement and the advertisement, or the public notification. Because ERMA requires that specificity, but from what you get, apart from the register, which is capable of simply requiring unique identification, one that can't – that means that this substance can't be confused with another, to requiring the identification of the chemical makeup of the substance.

MR BROWN QC:

Well, the wording, Your Honour has struck on the essence of it. And it comes from the wording of section 20(2)(b). If all that ERMA was looking for was, as I use in my submissions, if all that ERMA was wanting, and if all that Parliament was requiring the register contain, was an eartag with a number that no other animal, unidentified type of animal had, then it just needs to say a unique identifier, or it could, say, have the ERMA application code, or the ERMA approval code. Any number will do, if that's all that's required. But it didn't say that. It didn't say "a unique identifier". It said, "a sufficient description of the substance or organism to uniquely identify the substance".

BLANCHARD J:

So you're arguing that MEP 600 is not a description, it's merely an identifier?

MR BROWN QC:

Absolutely. And the Court of Appeal – and the key passage that we attack, and it's the ratio of the Court of Appeal's decision, certainly in the context of the approved question, is at page 77 of volume 1, under tab 6. It's paragraph 62. Paragraph 62 is a section that I spend some time considering in terms of the use of the word "identification", but the key part is the last four lines of

paragraph 62(a), because this is what the Court of Appeal said. "Section 20 is simply a direction to ERMA about keeping a public register. The need for a unique identifier in that context seems obvious. MEP 600 performs that function, although it is not, we accept, informative about the makeup of the substance". Now, that's the nub. And we challenge that, and Your Honours are asked by us to say, well, is that right or is that wrong? Is it an eartag with a number on it with a process there must be that no other number can be. It's ironic that the applicant can choose the code name. I don't know what insurance there is that another applicant mightn't choose exactly the code name. That's why I say that the ERMA application or approval number would be a better guarantee of it being unique, because at least ERMA could make sure that there wasn't a double-up, unless I come along in a few weeks' time and apply for MEP 600. But the question is, is that all that's here, an eartag, or is the requirement to sufficiently describe it to identify it? So say it's a Friesian, or a Romney, or a Merino.

MCGRATH J:

It's got to be something more than a label, and it's got to have a descriptive character.

MR BROWN QC:

Well, more than a label, which is a mask, not an identity. The code name is used, and purposely so, the code name is used in order to avoid describing or giving any information about the substance.

BLANCHARD J:

I suppose you'd argue that if it was Coca-Cola, that might uniquely identify it, but it wouldn't describe it.

MR BROWN QC:

It's uniquely identified, that's why I mention Robertson's J comment. It seems frivolous, but he's absolutely right. And that's the problem with this, and you see, that's the key, that's the short point. And if you say to me, well, where does the requirement derive, I say it's in the wording of section 20(2)(b),

because Parliament could have said a unique number, or any combination of words that said you've just got to have a number on there. As it happens, the register has it with the – it doesn't intend to do it, but having, as Her Honour the Chief Justice through her question showed, the register voluntarily has the application number and the approval number as well. But MEP 600, in our submission, it's not a case of it doesn't sufficiently describe, it doesn't describe, and that's an interesting word, "sufficient". Now, I agree, my learned friend the Amicus launches an argument that, well, "sufficient" depends on the context of the Act. I agree with that, too, and it's very much responding to Anderson's J proposition. Sufficiency will depend. With certain types of organisms, if we're talking about a genetically-modified organism, for example, there might be quite a degree of description that is required to be sufficient. Whereas for other things what is sufficient might be quite a simple exercise. But it is a sufficient description, and Parliament, in my submission, could never have used those words if it intended the eartag principle to apply. And that's our submission in a nutshell, really.

MCGRATH J:

But is the purpose of that language, and I understand the literal force of your argument, but is the purpose of that argument, that language really confined to giving certainty as to what the subject of the application is, rather than any sort of wider set of information, because that's provided down the track.

MR BROWN QC:

When you say it's "provided down the track", Your Honour –

MCGRATH J:

It's section 28 that's providing for that, is it not?

MR BROWN QC:

Well, not really, you see, the application process is conducted within ERMA, and it advertises, and people may or may not respond, like trademark applications or patent applications. Does someone put their hand up? Does everyone in the country sort of wander in and say I want to be heard on this?

Logically, the people who will respond will be trade competitors or the like, who have an interest, or, indeed, who are likely to have information about the management of these sorts of substances. But the register is entirely separate, in my submission. It is a register that compiles, and is maintained as applications come in. And Parliament intends that register to keep recording all this information. And if it was as narrow as might be implicit in Your Honour's question, you would wonder, then, about things like the purpose, and the project, and the controls, and the licences, and the permissions. It's a body of information that is, as it says, you know, in the ordinary office hours of the Authority, that is available for people to come and source. Now, I'm not going to move into the Official Information Act argument because, in my submission, that isn't contemplated by the approved ground. In fact, it was expressly not approved in terms of the three matters my learned friend Mr Goddard put up, and the one that was selected. But if you look at section 20(2)(a), and you look at purpose, and you look at project, and you look at controls, I could envisage, in theory, a situation where someone says, well, I'm going to apply for MEP 600, and purpose x and project y, and controls that deal with constituent elements a and c, as is in fact the case here. The controls say a and c. We don't know what they are.

ELIAS CJ:

But how could purpose be subject to the Official Information Act restriction?

MR BROWN QC:

Well, if a commercial entity persuaded ERMA that the purpose for which it intended to use it or import it was confidential, then there's no reason why it shouldn't be, because they say, and I don't want to – this is not my argument, but they say that 56 and 57 entitled ERMA to withhold any information.

WILSON J:

Mr Brown, doesn't 57(1) provide that if an application contains information which the authority thinks may be commercially sensitive, that information cannot be publically notified?

MR BROWN QC:

That's right, it does say that.

WILSON J:

Well, isn't that relevant to your argument, in that if such information cannot be publically notified, surely it cannot be included on the register, or otherwise the prohibition on notification is defeated.

MR BROWN QC:

That's my learned friend's argument.

WILSON J:

Yes, well, what's your answer to it?

MR BROWN QC:

My argument is that that provision does not contemplate within the reference to information anything that Parliament has required shall be on the register to be accessible. And it's interesting the use of the word "information", because it's a point I've made, and it hasn't attracted any interest before, but in section 28(2), when you come to deal with it, we get the application being the approved form and identification. Everything else afterwards is information. Possible adverse effects and the like. But as a base point, I say that section 57 can never have been intended to preclude the release to the public of what is the hazardous substance that is the subject of debate. And that is why we say, and we confine it to the argument of the register, that's what Parliament intends by the register when it says "sufficient description". See, this is the critical thing. The ratio – the Court of Appeal, of course, don't need to deal with that point in their judgement, because if they're right, that MEP 600 meets the words of sufficient description to identify, then they don't need to move into the – well, it isn't a sufficient description, but as a matter of confidentiality we won't publish it. What we're here about is the first point. We can't argue, we can't present an argument to you that if this is a sufficient one, it shouldn't be precluded for other reasons. We're here to deal with the proposition, is it

acceptable to have a register. And it will be a register for all time. It's not updated. There's no provision for updating it. It has all these masks.

ANDERSON J:

Does ERMA have the authority to impose a control requiring any packaging of an approved substance to state the name that was given on the application, and if so, wouldn't section 20(2)(b) be met by words which said, "This substance approved under application number xyz under decision number abc on such-and-such a date" as MR 600 *(sic)* or whatever it is. You don't have to identify a person by name, for example, if you can identify them by their current office. They're still identified. It's a question of being able to say, is this here equivalent to that there, on a register. It gets down to, what is the substance? Is the substance the sum of its parts, or are there a number of different substances, for example?

MR BROWN QC:

Well, I think the best way, because I'm not quite sure – there's two possible ways to do it. I think the best way to answer that question might be to take you to the controls for MEP 600. May I do that in answer?

ANDERSON J:

Yes, thank you.

ELIAS CJ:

Before you do, I'm still trying to understand the scheme of the Act, which I didn't have when I was reading the submissions, and I'm sorry for that. But is it the case that – I just notice the difference in section 28(2) in terms of the specification of what an application must include between the unequivocal identification of the substance, and then b, c, d, and e, which is all relating to information. And the section 57 formula is in respect of information supplied in relation to an application. Do you say that the 28(2)(b) to (f) matters can appropriately be withheld if the Commission isn't satisfied of the – but that the identification in subsection(2)(a) can't be?

MR BROWN QC:

I'm saying that those matters potentially could come within the meaning of information in section 57, although in my submission, as with the –

ELIAS CJ:

Well, I suppose the point I'm putting to you is, is it part of your argument that the section 57(1) expression in referring to information supplied in respect of any application justifies withholding some of the – what does it justify withholding? You say it doesn't justify withholding the identification of the substance?

MR BROWN QC:

No.

ELIAS CJ:

Does it justify, I'm putting to you, the withholding of the information of b, c, d, e, and f, which is part of the application, or do you take the high ground that anything in the application can't be withheld, it's only sort of collateral, non-core information that could be the subject of confidentiality?

MR BROWN QC:

No, I don't take the – it's not a high ground situation. I would be surprised if certain of the information in b, c, d, and e were withheld. But the reality is that this is all driven, in my submission, from article 39(3) of Trips, which is talking about confidential data packages. It's a requirement in Trips, and this is where my learned friend Ms Aikman wants to refer to the Agricultural Veterinary Medicines Act, that governments have to have a process for when they approve pharmaceuticals and the like, they provide for the confidential supporting information. And indeed, you get the flavour of it if you look back at section 55 of this Act, this is the section that makes the connection with the Medicines Act, and with the Agricultural Compounds and Veterinary Medicines Act 1997, and you'll see, for example, if you go to subsection 3 of section 55 in the penultimate line and the last line, you'll see the expression, "confidential supporting information". Now, I want to make absolutely clear

this is not a digging exercise by an entity to try and find out, as you recall that there's been litigation over the years, for example, I think in Fisor and Welkham about confidential information, and a pharmacy using confidential packs of one entity to support the product of another, and that sort of thing. Now, this is all designed, article 3 of Trips is designed, that if someone applies to register a substance in a country, you can't get access to all the experiments and the data and the approvals that they've undertaken. That sort of thing I regard as being off the page, and I would expect applications for confidentiality to be made, and sustained, in relation to those. My problem is with the proposition is that you can use this legislation to say, yes, we're going to conduct an application in relation to a substance, and you're not going to be told what the substance is. Now, I know Your Honour is saying to me how far are you prepared to go, and I'm back at the substance point. But I'm saying it isn't a case of core or the like.

ELIAS CJ:

Well, are you at the identification of the substance point?

1100

MR BROWN QC:

Yes, absolutely. I submit that if, when you come to look at this Act and if, on the question of what it means in section 20(2)(b) of the register, to answer Justice Wilson's question to me, I say that section 57 does not and never could be intended to enable ERMA to say, we're going to have a hearing, a public hearing, all the rest of it, and we're not going to tell you what the substance is. It's positively Orwellian when you think about the Minister's speeches of introducing the Act and the public involvement and all the rest of it and that's why we say the register is so important.

BLANCHARD J:

So you're arguing that for the purposes of section 57 a description of the substance of organism in terms of section 20(2)(b) is not information?

MR BROWN QC:

No it's not. That's the essence of the exercise. If it is information then nothing can – it's arguable that nothing can go on the register.

BLANCHARD J:

Describing it would seem to be a means of giving information on an ordinary use of the word information.

MR BROWN QC:

Yes.

BLANCHARD J:

But you're saying it has to be read down?

MR BROWN QC:

It has to be read down. Because of section 20, I mean I'm here about section 20 and not section 57. Now I'm – and –

BLANCHARD J:

Well you can't be and in terms of the ground, that's an untenable proposition. You've got to be prepared to answer the argument on section 57.

MR BROWN QC:

Yes, I accept that Your Honour. What I was saying, what I was trying to convey was that because of the, the reasons at pages 6 and 7 of the judgment of the Court framing the question that said, the approved ground is whether the Act requires the registered to –

McGRATH J:

So which paragraphs are we –

MR BROWN QC:

This is on page 6 of volume 1 of the case. It's the approved ground which is (b).

BLANCHARD J:

But that brings in section 57.

MR BROWN QC:

Well can I just explain what I'm arguing because I'm not saying it doesn't, I'm not saying it has to be taken into account but I have not deposed argument on it because of paragraph 2 over the page that said the second respondent proposed that leave to appeal also be given on the further grounds. They were those that were expressly about the release and withholding of confidential information and I have the memorandum here that list them and they were not approved. Now I'm not daring to say I'm refusing to answer questions because –

ELIAS CJ:

That was about whether it was a reasonable response of ERMA because they could have tailored the confidentiality orders. It's that fact that's off the table but the scheme of the legislation is very much on the table.

MR BROWN QC:

Of course Your Honour but the need, the need for ERMA to invoke its confidentiality powers in relation to the substance does not come into play if it's acceptable to have a code name that is said to meet that description. There are two layers to this. Does MEP 600 satisfy section 20(2)(b)? That's our first question. And if it does, if a code name that doesn't tell anybody anything is a sufficient description to uniquely identify then that's the end of our enquiry and the confidentiality powers aren't invoked. If, however, it is a case that Your Honours think that MEP 600 doesn't sufficiently describe the substance to uniquely identify it, that no it wasn't just referring about an ear tag but then well there's a question then about whether in terms of the application process, section 57 should justify not providing something that is a sufficient description, that's question 2 and that's where I'm coming from in terms of treating in a layered away. I certainly won't, I certainly don't decline to answer but my point about section 57 is that section 57, in my submission,

can't be treated as conferring ERMA with a jurisdiction to say we will, in practice, disclose nothing about an application.

BLANCHARD J:

But that's reading section 20 and section 57 in isolation. They surely have to be read together?

MR BROWN QC:

Yes –

BLANCHARD J:

Reading them together may still produce the result that you would wish but you can't just say, well you look at section 20 by itself and you decide what it means and if it means what I say it means then section 57 doesn't apply. You've got to look at both together.

MR BROWN QC:

Yes although –

ELIAS CJ:

And you perhaps have to also add in section 28(2) which is not necessarily something that is not unhelpful to you.

MR BROWN QC:

No, no I accept it is not. In fact my learned friend the Amicus, hope I'm getting that right, says that unequivocal and unique I think are really synonymous but I'm not at war Your Honour Justice Blanchard with the idea that these two don't come into play but –

ELIAS CJ:

The three I think.

MR BROWN QC:

Well the three, yes, and arguably in a way others that talk about identification of the substance as well but –

McGRATH J:

Mr Brown accepting of course that any relevant provision in the Act has to be taken into consideration, don't the phrases in section 57(1) "any information" and "in respect of any application" suggest that the section, the subsection is intended to be of wide import?

MR BROWN QC:

Yes I agree, I accept that. In fact my best, my best point, if I can put it that way, or it's my worst point, but my best point is that it's so wide that it protects everything, or can protect everything and that is why it's convenient that we are fighting this issue on the identity of the substance because that has to be the most poignant question in terms of the capacity to decline to disclose everything. That the – if there's one thing that people, in my submission, are entitled to know about in terms of matters of this import, hazardous substances and new organisms with the significance for people in their environment that I touched upon in sections 4, 5, 6 and 7, it is the identity as opposed to the non-identity of the substance.

McGRATH J:

Mr Brown, section 20 does not require that the application form part of the register does it?

MR BROWN QC:

No it doesn't.

McGRATH J:

So it has these elements that we're trying to ascertain the meaning of which would by way of summary of certain aspects of the application that have to go onto the public register.

MR BROWN QC:

That is right. But –

McGRATH J:

When you come then to section 28 it's clear that you have a more extensive specification of requirements in the application than you have in section 20?

MR BROWN QC:

Far more.

McGRATH J:

Yes. And part of that, is it not, is that the identification has to go not only to substance but to properties?

MR BROWN QC:

Yes that's true.

McGRATH J:

And properties isn't part of the necessary – isn't included specifically anyway as part of the section 20 requirements?

MR BROWN QC:

Absolutely not and nor is it actually a requirement that the, as I said before, the identification provisions of all the other sections doesn't have that bit.

McGRATH J:

But putting aside whether the MEP 600 et cetera label is sufficient, it's clear that the sufficient description of the substance can be something that doesn't have properties and might have to be more than the bare label we've got, but could be something that doesn't go into the properties at all?

MR BROWN QC:

Absolutely not. I've never contended the properties.

McGRATH J:

Couldn't it just be simply a generic say well we're getting this sort of product or that sort of product?

MR BROWN QC:

Well it, it will depend on how sophisticated or how difficult to describe. I mean I've got a –

McGRATH J:

Well couldn't it be for example, you're saying well we're dealing here with an animal drench and here say we're identifying MEP 600. In other words something more that tells you the general area you're in, wouldn't that satisfy section 20?

1110

MR BROWN QC:

Well, I don't really regard that as a sufficient description of the substance, and I think it's telling what the hazardous substance's identification regulations requires, which is in the controls, which is in the document that I was going to take Your Honour Anderson J to, because, you see, this is the scenario. This is a slightly temporal situation we're dealing with here. This is what is being said. Applications are coming in, and they're being processed, and approvals are granted with controls and then after a while these products will come on the market and the identification regulations require what's got to be on the labels and all the rest of it. All sorts of things are in the controls and relating to that and that is why both my learned friends who put this in a confidential box say this is a temporary condition because it's going to be public before long because you'll be able to go into Farmers or your preferred purveyor of agriculture chemicals or whatever and you'll see, it's on the label and I'm saying well this is bizarre that it's sitting there on the label and it isn't on the register because the register has got MEP 600. Can we, in that context, look at the, I'm not seeking to avoid Justice McGrath's question but I think the practicality –

McGRATH J:

It's certainly not helping me understand the answer to it just at the moment but –

MR BROWN QC:

Well –

McGRATH J:

– I'm sure that's probably me Mr Brown but I appreciate that this is sort of the basics, the differences in language and accepting a certain force in the literal approach you're taking but I do see a difference in what the requirements of section 20 and 28 are.

MR BROWN QC:

Yes, I agree with that Your Honour. I couldn't agree more that section 28 requires a great deal of detail that section 20 doesn't require. I was addressing myself to the question of what might be regarded as a sufficient description of a substance for the purposes of 20. There would be a plethora of information given under section 28 about the substance and its properties.

McGRATH J:

Yes.

MR BROWN QC:

All I'm saying is that in 20(2)(b) there needs to be a sufficient description and the point I was making was it's interesting to see what the controls require and perhaps, I'll only go to this once but could I take you to volume 2, it's the decision under tab 14, page 189. Now, we haven't looked at the statutory authority for controls but you should be aware that these are in part 6, under, part 6 is a heading "Controls" and it provides for hazard classification systems and requirements for labelling and the like, including identification. This MEP 600 is approved subject to controls and the controls start at page 199, appendix 1 and this is very relevant to your rubber gloves practical perception Chief Justice. There's a whole series of things here about, for example,

page 200, in the middle of the page, the limitation of how much of this can be carried in a passenger service vehicle, that sort of thing but you come over to page 202 and these are the requirements for identification of the product. Regulation 7 has identification, about a third of the way down, regulation 7 on page 202, identification duties of persons in charge and it requires the priority identifier information to be available to any person handling it within two seconds and the secondary identification information available within 10 seconds. Likewise in the next paragraph, the accessibility of information, priority within two seconds, secondary within 10 seconds.

BLANCHARD J:

Sorry, what is priority identifier information?

MR BROWN QC:

The priority is then listed in the next item Your Honour. Eco-toxicity priority identifiers are that it been prominently identified as being eco-toxic –

ELIAS CJ:

Sorry, where are we?

MR BROWN QC:

Bottom of page 202.

ELIAS CJ:

Oh yes.

MR BROWN QC:

Within two seconds being promptly identified as being eco-toxic, they must know that within two seconds. Then the secondary ones are in the next paragraph which is over on 203, this information must be accessible within 10 seconds and the information is an indication that it unequivocally identifies the substance which may include its common name, chemical name, or registered trade name. Then, if I can take you down, jump a paragraph and come to toxicity, secondary identifiers for MEP 600. This is a 10 second

requirement and this is an additional label detail and you'll see the last bullet point that says, the name and concentration of components (a) and (c). Now, of course, by the time this product comes to market (a) and (c) will be, well, bet known, ERMA knows what they are, we don't know what they are, the register has, would have, must have this on it somehow because these are the controls. Their argument is, well by the time someone comes to sell it, we've the marketing, we've got our things organised, on the label will be something within two seconds, something within 10 seconds, (a) and (c) will be identified, all the rest of it.

BLANCHARD J:

So the register will simply continue to refer to (a) and (c)?

MR BROWN QC:

Yes and MEP 600 because there is no provision for updating it and furthermore, whatever you may think about (a) and (c), if we're dealing with the ratio of the Court of Appeal I'm talking about, why would you update MEP 600 if it is a sufficient description to uniquely identify. In fact, I daresay that it would be unhelpful to introduce another unique identify, I think you should only have one unique identification on the register. That's why my learned friends say that this is a – if you look at my learned friend Mr Goddard's submissions, he says that this is a temporary confidentiality because you know, this will be public soon. So, it's almost as if we've got to keep this confidential material until the commercial company is ready for it to be known, so going through the application process it's confidential because some sort of order is made under section 57 but then it will expire, it won't formally expire but it will become public knowledge because if and when the product comes out there and that's the point I'm making, I'm saying well, did Parliament intend, in providing for a register, publicly available, to list the sort of things we're talking about, the description, the purpose, the protocol and the controls – oh sorry, the project not the protocol, the project, that is a word that comes from section 40, that's the new organism section.

That's why I say, to Justice Wilson I say, well if section 57 is the answer on the basis that any information is within it, then you could have a register that says MEP 600, purpose X, project Y, controls (a) and (c) and it may as well be in a foreign language, it has no –

BLANCHARD J:

Do we have regulation 25?

WILSON J:

Mr Brown, just while that's being handed up and in relation to the point you just made about my question, I've been looking at page 186 of the case on appeal, volume 2, part of the authority's manual and in particular paragraph 12 on page 186?

MR BROWN QC:

Yes.

WILSON J:

Would you have any complaint about the policy of the authority as said at paragraph 12 on page 186, I think it really picks up the point that you were just making?

MR BROWN QC:

Yes, would I have any?

WILSON J:

Any complaint about that policy in terms of the relevant legislative provisions? At first sight, it would seem to me to address the point you've made, in that it requires sufficient information to be publicly disclosed to make clear what the application is for, what are the likely risks, costs and benefits, and what effects a hazardous substance or a new organism may have.

1120

MR BROWN QC:

Well, I certainly think it's appropriate that information be publically available. But I don't – I suspect it's a little bit in the eye of the beholder as to what is sufficient and what is clear. I mean, my learned friend Mr Goddard, I know, and certainly Mr Upton would argue that, you know, ERMA is a specialist body. It has a sort of a pater familias on it. It knows about these things. Whereas I would submit that it may be fine as far as it goes, but it isn't a substitute for saying what it is. People are going to have to, in effect, try and guess what it is, or infer what the substance is. Not trying to infer what the formulation or the dosage regime or whatever it is, but, you know, is it particular – in the case of an organism, I can see that as being quite difficult, a new organism, which is defined as one that hasn't been in New Zealand before, or the like. Blanchard J, you were seeking regulation 25?

BLANCHARD J:

I was puzzling over why there would be any justification for withholding information on a temporary basis while the application was processed if it is going to have to be disclosed under regulation 25(e) before there can be any marketing of the product.

MR BROWN QC:

Well, I think my learned friends would say that getting through the HSNO door is the first door. It's sort of like, well –

BLANCHARD J:

It's not really a question for you.

MR BROWN QC:

That's a point I invoke, though. You say to me, quite rightly that, you know, you have to look at the Act as a whole and the interrelation of the sections, but the register is not a temporal thing, it is, as the heading says, something to be maintained. It's to be at a place, it's to be available to the public at these times, so that the idea that, well, the confidentiality that we're worried about for the applicant is only a temporal matter. That's where, I would submit,

there is a real disjunct in trying to relate those sections together. Unless, of course, you were to say, oh well, once the confidentiality is spent, then we go and rectify all these provisions in the register. But that doesn't help with the clear point that I'm here about, because if the Court of Appeal is right, there's nothing to rectify in MEP 600. That is, and always will be, a sufficient description of the substance. And that's why I say there's a flaw. And I say, then, and I'm jumping right ahead in my submissions here, but, you know, even emergencies aren't necessarily ordered emergencies. I say in my submissions that, you know, products that come in a labelled product get diluted into larger, generic products. In the case of drenchers, which we know this to be the case, they get put into dispensing things, sprays and wands and the like. Labels get destroyed. Products get spilled into waterways and drains, and are literally and metaphorically, or figuratively, a downstream problem. Now, you can say with my learned friend, well, the register is not the first port of call in an emergency. Well, that probably is right. Unless you've got a problem, you say, well, someone ring up and see what's on the register about this. What were the controls? Why, then, did Parliament mean this register as a sort of sterile functionary? That we've got all these applications so we'll put this collective body of information there that the public can look at it if they want to. That's when I find the driver that my learned friends push off, section 57, that you can have confidentiality for anything, really, that's important, like what the product is, in a register that says the public is entitled to this information is a dichotomy that's very difficult to resolve. And the Court of Appeal resolved it by saying, well, section 20(2)(b) is a very narrow requirement. All that section 20(2)(b) is requiring is, if I may put it pejoratively, an eartag. And that's what we are saying isn't right. We're saying it's more than that. How much more depends on the case. That's why the word "sufficient" is there.

ANDERSON J:

It's an eartag, but it's one that has to be attached to something.

MR BROWN QC:

Well, you don't get to know that –

ANDERSON J:

If you find an eartag in a paddock, it's not much use, but if you find it attached to a beast, then you know something about the beast. The problem that I have with this, the approach taken by the Court of Appeal, is that there's no correlation whatsoever between the substance in the real world and how you can search it. It's a public register that you can't even start with, unless you can relate it to something.

MR BROWN QC:

Well, I put to you a rather different and rather perverse scenario. There are luminous eartags, and you can see them outside in the field at night. You can't see the beast, but you know there's an eartag there, and there's something there, and it's unique, but you know nothing more about it. It's like a sort of a Braille tag to a blind man. It doesn't actually tell you anything about what the tag is connected to. And it's because of that lack of connection between the eartag and telling us something about it that I say the problem is. And that's not what I say the register intended. But how far the register intended to go is very much, very much instance-specific. Because the difference between, you know, we're here dealing with something relatively mundane, if I respectfully say so, agricultural drench. But the decision you're making applies to all new organism, including the most sophisticated matter than can be brought in, containment or experiments in containment. That's what this register is dealing with, and that's why it's so important that if it's saying a sufficient description of the new organism, are you content for it to be said, that's abc 123?

ELIAS CJ:

Is there a gazetting requirement in respect of this approval, or is it only in respect of some of the other approvals under this Act that there are –

MR BROWN QC:

Approvals on individual applications?

ELIAS CJ:

Yes.

MR BROWN QC:

I don't know.

ELIAS CJ:

That's all right. I just noticed that there is a requirement to gazette, I think it's section 49 or something, and I just wondered if there was anything –

MR BROWN QC:

They're the emergency ones.

ELIAS CJ:

There's nothing equivalent. So the register is the notification of approval?

MR BROWN QC:

Yes. Well, the notification of approval is the decision. The decision has to be publically available, that's in a whole variety of places, actually, but I think each relevant application says – if you look at, for example, in relation to section 28. The relevant provision dealing with the termination of the application, section 29, and section 29(2) says "the provisions of section 77 shall apply" – that's the whole control procedure, I haven't taken you through those sections – but then 29 says, "the Authority should give its decision in writing, including reasons for the decision, give written notice of the decision to the applicant and to every person who made a decision, and publically notify it". So there is a public notification of the decision, albeit it's a public notification of the decision in its –

ELIAS CJ:

Coded?

MR BROWN QC:

Yes.

ELIAS CJ:

Just while you're distracted, could you tell me what is the provision in the Act about notification of applications?

MR BROWN QC:

That's in 53. And I haven't wearied you with going into the First, Second, and Third Reading speeches about how important it is to be a public process, and the like. But there are a number of sections critical to that, and 53 is the public notification of applications. And you'll see in 53(3) that I took you to before, the public notice has to talk about making submissions, and a place where the application and company information may be reviewed. Interesting to see the juxtaposition, Wilson J, of application and information, because in my submission, this is very much a Trips construct of an application supported by information. And then there's the method of public notification, 53(a), and then there is, in 54, making submissions. Any person may make a written submission, shall state the reasons, the decision sought, whether they wish to be heard. And then, just to complete it in terms of the hearing, section 60 is the obligation to hold a hearing. Now, a hearing isn't absolutely necessary in all instances, but a hearing need not be held unless the Authority considers it's necessary, or the applicant has made a request, or a person who has made a submission states in that submission he wishes to be heard. So the real need for a hearing is if someone makes a submission and says they want a hearing. And in that instance, there is a hearing, as there was here, and that's section 61, provisions relating to hearings. And although I don't regard it as my role to draw you into the hearing process, because I think it goes outside the approved question that I sought, but section 61(7) says that the Authority shall hold any hearing of a public notified application in public, and shall establish a procedure that is appropriate and fair in the circumstances, may permit questions and clarification, permit only members of the Authority to question, and then the person is entitled to be heard who made the submissions. So it's a public hearing, but it doesn't descend to the detail. And that public hearing, of course, was held, but all in the environment of MEP 600. The decision is MEP 600, the advertised approval is MEP 600.

And my learned friend's argument is, well – I think the argument is, and I don't mean to belittle it, but don't sort of worry about that, because it's a temporary confidential constraint, because eventually the product will be marketed, we'll know what it really is, we'll know what the controls are. In the real world, a real world spill, it's sitting on the label, and our rhetorical question is, really, well, what about the register? Does it sit there as a relic of the process whereby it was dictated by confidentiality? And when I say dictated, the register has dictated if ERMA is persuaded, as it was here, and, I might add, would seem to be persuaded in the majority of section 28 applications, that the actives shouldn't be disclosed.

COURT ADJOURNS: 11.33 AM

COURT RESUMES: 11.50 AM

ELIAS CJ:

Mr Brown, do you have in the case on appeal a copy of the public notification?

MR BROWN QC:

No.

ELIAS CJ:

How was it notified?

MR BROWN QC:

May I just confer with my learned friend?

ELIAS CJ:

Yes, sure.

MR BROWN QC:

I'd have to leave that to my learned friend, Your Honour. I don't recall that in any of the Courts there was actually on the record any evidence of how the

notification took place, other than the actually decision. We did have the call for submissions, but we didn't have that.

BLANCHARD J:

Is the call for submissions a statutory requirement?

MR BROWN QC:

Yes, I think it is. In 53(3), it says the public notice, and you'll recall we took you to that, the public notice shall state any person may make a written submission, and a closing date for receipt of submissions, and a place where the application and the company information can be viewed, and the address for the Authority, and the applicant, unless the information has been withheld, et cetera.

BLANCHARD J:

But the call for submissions is something separate from the public notice, isn't it?

MR BROWN QC:

Yes, it is. Sorry, did you ask me if the call for submissions –

BLANCHARD J:

Yes.

MR BROWN QC:

I don't recall that there is an actual statutory provision providing for the –

BLANCHARD J:

So they advertise it twice, effectively?

ANDERSON J:

53(a) deals with the method of public notification.

ELIAS CJ:

That's whether it's in a newspaper, or on television, or something of that sort, is it?

MR BROWN QC:

The call for submissions states that the applications have been publically notified, and of course they would be on the website.

ELIAS CJ:

So do we have that, at least, the call for the submissions?

MR BROWN QC:

Yes, the call for submissions is the document at page 111 under tab 11 in volume 2.

BLANCHARD J:

That says date of public notification 5th of July 2006. This was published on that date, yet it talks further up about have been publically notified.

MR BROWN QC:

That's right.

BLANCHARD J:

But this isn't the public notification. Yet they're setting it – they're talking about the same date for the date of public notifications.

MR BROWN QC:

It says at the bottom that the former public notice, and any further information can be obtained, et cetera. So it says how to get it.

ELIAS CJ:

You should go onto the website, perhaps. 53(3), the place where the application accompanying information may be viewed at the address, unless

that information has been withheld. It does seem to be a potential argument that the application is a bit different from the accompanying information.

MR BROWN QC:

Yes, that's the position I take. And indeed, my learned friend wants to refer to the Agricultural and Veterinary Medicines legislation. That actually uses the two terms. The application and the supporting information, and it's the supporting information that has the period of time for not being able to be released. And that is why that article 39(3) in Trips is so material, because these things are responsive to that, that you can get your registrations all around the world, but you don't have to disclose your packages. I mean, it's much easier when you think of a pharmaceutical, where you've had your trials and you've had all these things to satisfy the regulatory bodies that these things are safe, and the like. You're field testing. You don't have to disclose that sort of material, because that is commercial information. Someone else should have to go off and do that. The public aren't –

ELIAS CJ:

I'm not familiar with article 39. Is it relevant?

MR BROWN QC:

39(3).

MS AIKMAN QC:

If I could assist, I have made copies available to the registrar, and was going to address those later.

ELIAS CJ:

All right, we'll see it then, thank you.

MR BROWN QC:

But I do say, and the problem that I have, and that's why I said my best and worst point to Wilson J, is that information is used just as that word in section 57, on the face of it, anything that is information, anything is information, and

information is able to be withheld. And that was I thought Wild J thought it sat. That's why his decision said, well, there's got to be confidentiality undertakings, and this is unworkable if you can hold back things like this. And he went the confidentiality undertaking route. And that was the cross-appeal by Ancare in the Court of Appeal, and they ruled against that as well. So we're right back at step one.

ANDERSON J:

What if Joe Public came along and they said, well, we're not going to release it to you personally, but we'll release it to your lawyers. Poor old Joe can't participate in that situation, but the monied people can.

MR BROWN QC:

Yes, those who can employ the scientists or whatever who know about the product. But, of course, the reality is that it's the companies who have the scientists and who can say whether something like, say, moxidectin or something.

ANDERSON J:

I understand that, but the policy must be applicable to any member of the public, not just those with the commercial interest.

MR BROWN QC:

That's right. And you do have to say, if this register is for the public, working from the bottom, if it's saying here are the controls, and here is the project, and here is the purpose, then when you come to sufficient description, there's something odd about that.

ANDERSON J:

Was there anything that requires the information in the register to be entered before a disposition of an application?

MR BROWN QC:

No.

ANDERSON J:

It could be written up afterwards. It doesn't fulfil the notification function.

MR BROWN QC:

No, it doesn't. And that was one of the puzzling things about the Court of Appeal's decision. In paragraph 10 of the Court of Appeal's decision, and I just say this so you're aware of their thinking, it's at page 59 of volume 1 of the case. The Court of Appeal said this. Essentially, there is a public notification process, followed, generally, by a public hearing to facilitate the public nature of the process. ERMA is required to keep a register of all applications made to it. So the Court thought that the register was part of the process, and I don't accept that can be so, especially the last items, where it talks about was it approved, and giving notice of the controls. They're only known once the application has been decided upon, and the particular controls imposed. And although I know we can't look at the heading, but it is to prepare and maintain a register. So the register has an ongoing function. It's not a functionary of the hearing process.

ANDERSON J:

What your client's concern is, really, is the way in which the confidentiality sections operate and practice. It's a section 20 attack on section 57, isn't it?

MR BROWN QC:

Well, my client's concern, Your Honour, is that the playing field be established so it's level. Either we all put code names in, or none of us do. At the moment, it's 60 percent. If ERMA's persuaded that if someone says, look, this is, you know, until it hits the wooden floor of the co-op, I don't want people to know about exactly what it is, or whatever, then – look at Mr Goddard's submissions. He's got two charts. We know from the second chart that it's only a section 28 application, so it isn't for all of them, but roughly 60 percent, 59.5 percent, are code names. Well, we're here to find out if that's all right. Because if it is all right, there'll be 100 percent code names. But if it isn't, then we're back to a description, and the question will arise of true confidential

issues if section 57 extends that far. But when you say my client's wish, well, I think it's the industry's wish, is to know. And I suspect it's ERMA's wish, as well. And the Court of Appeal's decision, the ratio that I'm here about, says a code name designed to not provide a sufficient description, that's fine. That's all we will expect to hear.

WILSON J:

Mr Brown, just looking at volume 2 of the case on appeal, under tab 8 we have the application, it seems to be about a 16-page document. And under tab 9, what's turned in as the application summary, that might be said to be a fairly anodyne document. Is it the application summary which is publically notified?

MR BROWN QC:

I believe that's so. A much more extensive – my understanding, and it's only my understanding, is that a much more extensive disclosure is given to various government agencies. They get it. But the non-government people get a much abbreviated one. Just how abbreviated, I'm not sure. But I think it's along the lines of the summary. But then my learned friends will say, well, the register gives you windows to go to. If you look at the document that we looked at, that last page, the MEP registration on the website, you can go to various documents. You can go to ERMA's review document and the like, suitably protected. So they say that there is a lot of information will be voluntarily provided. And that's interesting, but it's not really material to, in my submission, the meaning of section 20(2)(b), because they may or may not provide that. It may or may not be looked at. It can't, you know, it doesn't matter how helpful you say you are or how user-friendly, what we're here to do is what Parliament required that register to show. I've pretty well canvassed my argument. I'd just like to close with a couple of points that perhaps bring out items that elucidate some of the more technical things, and one of them is the Bomac application, which was initially a code name, and then when information was requested, Bomac provided it. And it will show you, for example, what a CAS is, a chemical abstract register. If I can take you to this one example of another code name, what happens when someone

says we won't code name it. If you go to volume 3 of the case, tab 15, pages 236 and 237. The reason I'm taking you to these is these are, in my submission, up until the time that another entity requested it, what this application was, if you look at the heading RAYHSR06094, that's the HSNO application number. And then there was the code name that Bomac had used. It looks a pretty exotic name, but it's simply an alphanumeric code. None of those numbers or letters stand for anything that conveys anything. And then when they were asked, they said, no, this is what we're applying for. So they gave the active ingredient, that's in the left column. The chemical abstract services registry number, that's a number that's a unique number for a compound, and the chemical structure. So they may say they rather overdid it. They gave all three. The reason I refer to it is that the CAS registry number you'll recall is one of the items that was listed in the controls as what are required when you unequivocally identify it, trade name, CAS number, and the like. So these are all various ways in which you could uniquely identify, you could give a sufficient description of the substance. This is an informative number.

ELIAS CJ:

What is the CAS registry?

MR BROWN QC:

It's a chemical abstract register.

ELIAS CJ:

And what's that maintained under?

MR BROWN QC:

By one of the scientific organisations, Your Honour. It's a multinational chemical –

ELIAS CJ:

Classification?

MR BROWN QC:

Yes. And interestingly, ERMA recognises that, and that's what was in the controls that we looked at, and for your reference, it was dealt with by MEP 600 and with ANC. If you go to pages 205 and 206 of volume 2, and this was the information dealing with regulation 39, so in the bottom third of page 205 in volume 2, you'll see regulation 39. General content requirements for documentation. The documentation provided with MEP 600 must include the following: the unequivocal identity of MEP 600, e.g. the CAS number, chemical name, common name, UN number, registered trade names, and if you come over the page to the top of the next page when it's dealing with components A and C, which actually are in bold, it's the name, concentration and CAS number of components A and C. So they are in the trade, so to speak, ways that you can identify something, and which are recognised in ERMA's own procedures. And that all should be sitting on the register, whether it is or not, it should all be sitting on the register. They're the controls, albeit with the A and C code. So that's the Bomac example, and that's why I say, in my response, slightly emotional, perhaps, to the section 57 argument, is that the register should not be a result of happenstance or the whim of commercial applicants who say, yes, until I've launched, I'm going to have a code name for the substance. If the register requires something different, or, as I say, at least everyone can do it. But the problem, if I put it that way, that the Court of Appeal presented us with, is the finding that MEP 600 satisfies the words of section 20(2)(b). And my learned friend the Amicus' argument on that is interesting. It's paragraphs 50 to 54. Because in my submission she sort of starts off with me, and then ends up with the Court of Appeal. Paragraph 50, she agrees that the phrase needs to be read as a whole, composite phrase. She then says that sufficiency needs to be assessed in terms of the register's purpose and the context of the Act overall. Well, I agree with that, although we have a very different view about the purpose of the register. Then follows the proposition that the register is not the first port of call in an emergency. Well, in contrast my learned friend Mr Goddard's submission at 41 that the register is the initial point of call for information, applications and approvals. But then it's at 54 that I have the problem, because the submission says at paragraph 54 says that it contends that a

"sufficient description required is no more than necessary to uniquely identify it". Well, I agree with that, in the sense that we are talking about a description there, still. But we're talking about the sufficiency of it. But then, at the end of 54, there's the quantum leap to the submission that the words "sufficient description" do not add any further requirements to the need to uniquely identify the substance. It is said there that the description is sufficient if it is a unique identifier. Now that's circular and that's really no more than what the Court of Appeal said. It involves no element of description and it gives no meaning to the first half of the paragraph, so that's our primary concern.

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I've dealt with, in my submissions, identity and identification. I would draw your attention to why we say the Court of Appeal's decision on identification is not useful and therein – I won't read them but they're in paragraph 61 to 68 of our submissions. There's a very, well it maybe an elegant argument but it's a very complicated – an argument that the word identification, perhaps I should take you to that. The Court of Appeal, if we come –

ELIAS CJ:

This is your argument?

MR BROWN QC:

Yes, it's at my argument at 61 to 68 and it's the Court of Appeal's paragraph 62 again because 62 on page 77 seems to be where the real finding is. Basically, you need to have, you need to look at the definition of identification in the Act for this. Your Honour the Chief Justice has made the telling point about what substance means, well identification as a definition is problematic as well because it lists a whole series of things which it means. What I was focusing upon was the first of the things that it means. It means, if you look at the definition of identification it says, "clearly identifies the chemical or biological nature of the substance or organism" and I said to myself well, you are actually identifying something there, that identifying there is subject matter not, it's the face not the mask, it's dealing with the substance but the Court of Appeal said well, we don't find that definition of identification helpful because it has all these other things in it and they say that the definition, this

is at section 62A, they say, "The definition of identification doesn't contain the words and identify has a corresponding meaning." Therefore, they say well, identification, um, they seem to say, it can't be dealing with either section 28 or 20, that's what they say in the next paragraph although 28(2)(a) uses the word identification, the extended meaning seems inappropriate.

In my submissions I've listed all the different places where identification and identify are used and I find the argument that they make there difficult because you'd really have to wonder for what part of the Act the definition of identification was placed there if it's not applicable to these provisions. In any event, they've two reasons there that they say it isn't helpful to look identification and all I'm saying is well, if you look at paragraph (a) which is talking actually about the substance part as opposed to other things, precautions and type of hazard and aids in managing, that's giving us a bit of a steer that when the word identifies is used it's contemplating subject matter.

Likewise then, the Court of Appeal's, at paragraph 66, were dismissive of my argument by reference to the hazardous substances identification regulations. They say that they contained detailed identification requirements but how they dealt with it, they said these regulations were made under section 76. That section is found in part 6 which deals with the control of hazardous substances rather than with the application process. Now, the trouble with that is that the control, this part of the application process, the controls are how you, that's how you put parameters round the application. That's why section, we looked at the, you asked me about the section 29 that said where is the decision publicly notified, it's section 29(7) that says the provisions of section 77 shall apply to any substance approved and section 77 is the controls section.

So the Court of Appeal seem to be looking at this Act in compartmentalised way. They say it isn't very helpful looking at the regulations, they're made under part 6, that's about controls but controls are an integral part of the application, or the approval and they end up sitting on the register. The last two items in the register entries are the controls and yet we have,

paragraph 66 it says well, that's dealing with controls rather than the application process and I find that an unsatisfactory way to counter that argument as well, so –

ELIAS CJ:

You just slid in what you said from applications to approval?

MR BROWN QC:

Yes.

ELIAS CJ:

Is the point that the application – when you say that a control is integral to the application, do you mean it's integral to the approval process?

MR BROWN QC:

Well it's integral to the determination of whether or not –

ELIAS CJ:

Yes.

MR BROWN QC:

– an approval is granted. It's defined, control is defined in the section 2(1) as meaning any obligations or restrictions imposed on any hazardous substance or new organism or any person by this or any other Act. ERMA actually recommends the controls. My learned friend, Mr Goddard's submissions, refers to the controls but at that part of the documentation that has ERMA's recommendation and the actual controls then are those in the appendix to the decision. It's like granting something subject to a condition, if the controls weren't imposed then the approval would never be granted and the application would fail, so they're fundamental to it. They end up on the register and yet the Court of Appeal said that, you know, when I'm looking at how they identify what we've looked at, the CAS, the chemical number, the like, they say well that's dealing with the controls rather than the application process.

Now I'm not quite, perhaps they saw the application process as being something much more contained but by the application process, I would submit, it's the application, it's the advertising, it's the submission, it's the public hearing and it's the granting of the approval, otherwise with the controls it would end up on the register. So I submit that to the extent that there was weight in the submissions that I presented on the basis of either the identification regulations or the definition of identify, that the way in which the Court of Appeal rebuffed those submissions was most unsatisfactory.

That really is the totality of what I have to say. I had a miscellaneous point at the end to deal with the unique equivocal, unique and unequivocal point but of course I've made it clear in the course of my submissions that we have never been contending that the substances properties referred to in section 28(2)(a) were the part of this application. It's limited to the substance and in a case where it might be two, where the documents itself identify for example two critical components (a) and (c), the sufficient description might be saying substance containing these two. After all, they're the things that the controls are about, they're the things that people are expected to respond to, so they've got these controls, they really perhaps ought to know what those two nasty bits inside are what they need their gloves for and the like.

Unless there are any further questions, that really concludes what I have to say.

ELIAS CJ:

Thank you Mr Brown. Now Mr Goddard, were you to go next or have you conferred about order?

MR GODDARD QC:

I have conferred with my learned friend Ms Aikman. It's probably more logical for her to go next Your Honour and then for me to assist on any limited matters of information that I can at the end.

ELIAS CJ:

Yes, thank you.

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MS AIKMAN QC:

Thank you Your Honours. Your Honours, I wonder if before I start on my submissions proper, it may be appropriate to take you to the two supplementary documents which I've just made available and I apologise, they've only just been brought to my attention. I'll start with the Agricultural Compounds Bill which I will submit is supportive of my argument that the HSNO Act should not be dealt with in isolation but also considered alongside the framework of the Agricultural Compounds and Veterinary Medicines Act... This is the report from the select committee, and as you'll see in the first sentence after the background, the committee notes that "this Bill is part of a wider reform of agricultural legislation, and there is a companion measure to the HSNO Act". It then goes on the following page, there was some discussion about whether there was a need for a separate Bill from HSNO, but the committee concluded that the Agricultural Compounds Bill in the HSNO Act do have different purposes, and that not all agricultural compounds are hazardous substances. So some could go directly, and, indeed, do go directly, to application under the Agricultural Compounds Act.

ELIAS CJ:

The hazardous substance legislation was substantially amended in 2004, was it, or '05?

MS AIKMAN QC:

I don't know if it was in relation to this aspect. Certainly the Agricultural Compounds Act amended – inserted the provisions that my learned friend has already taken you to in section 55. There is a particular regime under the Agricultural Compounds Act in relation to innovation agricultural compounds. There is a parallel provision under the Medicines Act, and they were inserted into the HSNO Act, and we'll come to that. That was part of the whole Trips compliance. Then on the page headed VIII, at the bottom of that page there was the heading, "Disclosure of significant new information". And it reads,

"We considered options for including provisions that would require disclosure of significant new information about the effects of a product. In particular, we wish to ensure a person should continue to import, manufacture or sell the product. Where that person is aware of significant new information", so, again, there's an information concern. But perhaps more relevant is on page X, which relates to information protection, and it's in response to a number of submissions regarding the adequacy of the protection under the GATT Trips Agreement, trade related intellectual property rights, and relates to the public release of test data submitted for clearance of an innovative compound is to be precluded, and therefore suggests in the Agricultural Compounds the insertion of a new clause, 11(a), which parallels the provision in the HSNO Act that where there is information for which an applicant seeks confidentiality that there is a process of consultation with the submitter and then a decision whether to release that information. And as it notes, there's a consequential amendment for the HSNO Act as required. Now, this was in the context of innovative agricultural compounds, and there's no suggestion that this particular MEP 600 comes under that category. The components of MEP 600 have already individually been approved by HSNO. It's just the particular combination that the applicants were seeking confidentiality for. But I bring it to your attention because what works for this one must work, also, for innovative agricultural compounds and medicines and the register must apply the same rules for all. So that this is a particular regime that may exist for agricultural compounds other than MEP 600, which gives rise not only to obligations under the HSNO Act and the Agricultural Compounds Act, but also at international law. And therefore I also included in the materials handed up an extract of the Trips agreement, and as my learned friend has already indicated, Article 39(3) makes it mandatory for members when they require an applicant to disclose certain properties, new chemical entities, in order to have approval for marketing of that product, then that information shall be protected against unfair commercial use. However, there is an exception where it is necessary to protect the public. So I'll come, in the context of my submissions, to those documents, but I think they are relevant to the overall scheme of HSNO. And that was – Trips was 1994, I think it came into force in 1995. So it was very much involved when this legislation was being passed.

My submissions are that it is plain, both from the plain wording of section 20(2)(b) and its context, that the register is not contemplated to include a description of the components of a particular substance, and like my learned friend, I will start with section 20 and then work my way through the Act and broader context. Starting with the words that it must be, in 20(2)(b) "a sufficient description of the substance to uniquely identify it". My learned friend suggested that because the choice of an identifier is in the hands of the applicant itself that one could have, theoretically, two with the same identifier. Well, that, of course, will not have met the test of being unique, and would be promptly rejected by ERMA. It would be somewhat similar to the registration of company names. I submit that the Court of Appeal was right to say that all that is required is a unique identifier that will distinguish it from any other one, that those words "sufficient description" add nothing more to that. The emphasis must be on the 'uniquely identify". And as the extract from the register, which Your Honours have already been taken to, which is at tab 18 in volume 3. You will see that on the register it is no more in that case than a heading, and my submission is that the important parts of it are not the heading, which is of limited length. Even on my learned friend's submission, it would be unlikely to see a very full description of the product at that point. The key parts of the register are those which appear below. The substance documents, the application documents, et cetera. And again, the register on its actual face gives very little information, but it does give, in its electronic form, certainly, very ready access to the documents that really count, the application, the control, and E & R Report, and other matters. I note in my submissions that the internet version is not a statutory requirement, so the extent of the statutory requirement is that somebody can go into the office and search the register physically, and presumably they would find on that those documents, including the application.

ELIAS CJ:

The application will exclude, because –

MS AIKMAN QC:

The confidential material.

ELIAS CJ:

In the index.

MS AIKMAN QC:

Yes. The key part, in my submission, if one is looking for further information about the product itself, will be in the trade name. And you'll see in that extract that it doesn't actually give a trade name. It may be that MEP 600 doesn't have a trade name yet. But that will become its major point of reference once it has one, and if you wanted to find out more about the product, in my submission, you would look at, you know, it might be something like Super Animal Drench, or something like that. That is where you would go, apart from looking at things like the label itself.

BLANCHARD J:

But does the register get amended once there is a trade name? Because the trade name may not be invented until after the application has been approved? Very likely won't have been.

MS AIKMAN QC:

Perhaps my learned friend Mr Goddard could help you on that. But as Mr Brown has said, ERMA's obligation is to maintain the register, so one would have imagined at that point a trade name would be inserted.

ANDERSON J:

How do they know?

MS AIKMAN QC:

How does ERMA know?

ANDERSON J:

Yes. How would they know? There's no provision for notifying trade names. And what's the use of MER 600 *(sic)* if nobody knows they're looking at it? What's the use of the register, then?

MS AIKMAN QC:

I think probably the use of the register is, as I've suggested, not a point of contact for people wanting to know about the product in general. It's not if you were an end user of this Super Drench, or whatever it's called. But rather it is really a check for those who are in the know to see where it's got to. It's got to the application phase, it's got to the E & R phase, or it's been approved or declined. In many ways, it's maybe a check for ERMA itself.

ANDERSON J:

No, but it's for the public. It's not for ERMA's benefit. It's for the public's benefit. And if you don't know the particular product is MER 600 *(sic)*, what's the use of the register? It's meaningless.

MS AIKMAN QC:

I'm not sure – because it comes in part 4 of the Act which sets out what ERMA's – the parameters of establishing ERMA and its obligations, and it comes, one of its obligations is that it must maintain, or may maintain, certain registers, and this is one of the compulsory ones, that it may actually be a machinery, largely a machinery provision for ERMA. The public part of it comes under part 5, where there is the requirement to public notify, to receive submissions, and matters like that.

ANDERSON J:

This register anticipates that it will be functioning after disposition of an application.

MS AIKMAN QC:

Yes, yes.

ANDERSON J:

So the hearing process has got nothing to do with it. It's what's the purpose of the register. Now, if, invariably, a requirement of approval was that one had to put on any packaging ERMA application MER 600, *(sic)* then anyone looking

at the product can use the register to trace it through. But if you don't know what MER 600 *(sic)* is, because it never has that name on any labelling, the register is useless.

MS AIKMAN QC:

I'm not sure whether, once it has a trade name, whether it's searchable by way of trade name, in which case that would be a route into it. But my submission is that the primary source of information, you begin with the label, and the label will have the controls on it, and that will have, in detail, what substance A and C contain, and it will have measures such as, must be dispensed with masks or gloves, or things like that. It will have, for instance, if it's spilled in the waterway, or a child has ingested it, or something, will have emergency contact numbers, a reference to the Poison Centres, a reference to the manufacturer, so that these are the things that will happen most immediately. And those are evident from Mr Brown taking you to the controls, so within two seconds, if you've got the label, you can understand this. If you don't have the label, which is also possible, you might know the name. But you wouldn't probably go to ERMA first. You would go to things like the Poison Centre, or -

ANDERSON J:

I understand that. That's why you label it. That's the purpose of the labels. I want to try and get my mind around what is the purpose of the register, being a public register.

MS AIKMAN QC:

Well, I think, like a number of public registers, it may serve a number of purposes. I see it primarily as a checklist. Anybody can look up the register and see where the MEP application has got to, that it's been approved. ERMA can, perhaps, see, well, we've had, you know, 63 applications this year and we've approved so many and declined so many. And it happens to be open to the public, because there's no reason why it shouldn't be open to the public. But that doesn't necessarily mean that its primary purpose is to be open to the public, is to be a source of information for the public. So that is

why I think that in all likelihood, it will be competitors, the applicants themselves, government departments, who will use this register, rather than members of the public, but they are not precluded from doing so.

ANDERSON J:

Who is meant to identify it?

MS AIKMAN QC:

To identify?

ANDERSON J:

The substance. It has to be identifiable. Identifiable to whom?

MS AIKMAN QC:

Well, it must be identified in the application made under section 28.

ANDERSON J:

It's the register I'm talking about, section 20.

MS AIKMAN QC:

You then come back to the unique identification, and what is sufficient.

ANDERSON J:

And who has to – for whose benefit is it to be identified?

MS AIKMAN QC:

I think at this stage, it's purely a machinery identification. I mean, as MEP 600 is uninformative, the one that Mr Brown took you to which he referred to later as Bomac, which was a very long alphanumeric, was even less helpful. It's not something that you could even say easily. It's not intended to be – remember, although this register applies to section 28 applications, it also refers to other applications as well, in particular applications under section 31, which is bringing items in for, in containment.

ELIAS CJ:

What does that mean, in containment?

MS AIKMAN QC:

That it's not for distribution. I think, although it applies to substances, it's particularly to new organisms, where you might be testing new organisms and they would have to be places where there was no chance of cross-contamination and things like that. So at that point, there may be very little known. There is a definition of containment, "restricting an organism or substance to a secure location or facility to prevent escape, and includes, in respect of genetically-modified organisms, field testing and large-scale permutation". So a pharmaceutical manufacturer may be bringing in substances that have no trade name, are very much at an experimental stage. They still need to put it on the register, and have an approval, although not the same degree of public notification as exists as section 28. So it is a register for all purposes. Yet you would not expect the same need for public – the Act does not expect there to be a public submission process in section 31. And it might help if I took you to that section.

MCGRATH J:

Is it important, if you are using a label such as MEP 600, in specifying the purpose of the application under section 20, you say something more about what it is?

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MS AIKMAN QC:

I would read that as, you know, it's been brought in by the manufacturer as an animal drench, or something like that. And you'll see that in the extract from the register, MEP 600, to manufacture and release it for use as an anthelmintic in liquid form for ruminants, that's the purpose.

McGRATH J:

Well is that, I just really wondered if that was why ERMA was insisting that something more be said about it in light of that comment which is of course the most informative at least on this page.

MS AIKMAN QC:

Yes, that ERMA was insisting that more should be said?

McGRATH J:

You've got to, I suppose, and I think that Mr Brown was really saying this, looking at what you specify you've got to read everything together and you're certainly, when you're looking at sufficient description of the substance you may have some of the description actually in the statement of purpose.

MS AIKMAN QC:

Yes.

McGRATH J:

Particularly if you've just got one of these labels.

MS AIKMAN QC:

Mmm and you would indeed have quite a bit in the application itself and he's taken you to the application minus, minus the confidential material so –

McGRATH J:

Certainly yes, yes the electronic links would be important, I accept.

BLANCHARD J:

Was your point about section 31 that public notice isn't required under section 53?

MS AIKMAN QC:

Yes. And in terms of –

ELIAS CJ:

Sorry I'm just trying to understand that.

MS AIKMAN QC:

You must still show – have the purpose for – in 31(2), so there must be identification of the substance and as MR Brown has said it doesn't use the words unequivocal or anything, it just simply says identification. The purpose for which it is sought in other matters such as, there's quantity.

BLANCHARD J:

So a section 31 application is not a public process?

MS AIKMAN QC:

No. But it must be on the register so the public can find out that such an application has been made. They can then search the application but they're not alerted to it in the same way as they are under a section 28 matter. so one would assume that people who are particularly interested in this matter, and that would not only include competitors but government departments and perhaps groups who are concerned with things like genetic engineering and other environmental matters, would be regularly looking at the register.

ELIAS CJ:

Well it's really public notification is required for products or substances that are going to be released.

MS AIKMAN QC:

Yes.

ELIAS CJ:

So I'm now trying to recall why section 31 is relevant?

MS AIKMAN QC:

It needs to – section 31 applications need to be on the –

ELIAS CJ:

On the register.

MS AIKMAN QC:

– section 20 register.

ELIAS CJ:

Yes.

MS AIKMAN QC:

So it supports the argument, in my submission, that the, you have one regime dealing with applications for manufacture and release which is dealt with under part 5 and you have the release of information or otherwise provisions under that. The register has quite another purpose. It is a machinery part of ERMA. It has to keep a number of registers as part of its statutory function.

ELIAS CJ:

But is it either/or? Is it really, as Mr Brown would say, is compartmentalised?

MS AIKMAN QC:

I think its primary purpose is a machinery one. That doesn't mean to say that is its sole purpose. It is available, quite clearly, to be searched by the public but it is not the main source of information to the public. It is perhaps a doorway in if you go to the register and if you happen to know that you're looking for MEP 600 which you probably wouldn't.

Perhaps if I could then take you to part 5 which although my learned friend has not placed the emphasis of his argument on part 5 in my submission it is absolutely crucial to understanding the Act as a whole and therefore the purpose of the register in section 4. So one begins with an application being made under section 28(2)(a) and that is an unequivocal identification and I, reviewing my submissions yesterday, I noted that I'd said that the two were synonyms. I don't believe they are any longer. I think that something could be unequivocally described and yet not be unique and it could, or it could be unique and not unequivocal, so the two do have a different purpose.

ELIAS CJ:

Yes.

MS AIKMAN QC:

I think the difference, however, is, and I think that this is accepted, that it is not just identification of the substance, but its properties as well. Properties are not defined. I'm not sure whether that refers to such matters as the chemical properties, for instance the structure diagram that Mr Brown took you to might be one example of properties or it might simply be a reference to the fact that it's eco-toxic or it's flammable but whatever but certainly it does require a full description and the regulations make, add to the Act in that respect and make it very clear that it must be a full enough description to enable ERMA to carry out its functions.

BLANCHARD J:

Does unequivocal simply mean full?

MS AIKMAN QC:

Well leaving no room for doubt I suppose.

ANDERSON J:

Something you can't equivocate over.

ELIAS CJ:

Quibble about. Argue about.

MS AIKMAN QC:

And quite why the Act has used unequivocal in section 28 and not in section 31 I don't know that there's any particularly logical answer to that but perhaps it does serve to emphasise the point where you are going to manufacture and to distribute an item you have to have all the information possible.

My learned friend also drew them, drew to the definition of identification but again such definitions are always subject to context in the Act and I don't

really think that that definition helps. It's a very full definition in section 2 and yet it is used liberally throughout the Act to apply to matters that don't cover that full range right down to controls and how to contact the manufacturer and things like that. So the drafter must have thought it had a purpose at the time but I don't think it helps in this context.

We then come to section 57 which is the ability to limit information and one begins with the – or perhaps section 55 is the start that the applicant may seek confidentiality of certain information. And I think, picking up some of the discussion earlier today, it is not any information at all, it has to pass the test of section 9 of the Official Information Act that it is trade secret or commercially sensitive so it would be hard to see that information for instance about disposal or other matters would give rise to questions of trade secrets or commercial sensitivity. Those issues are only likely to arise in relation to the compounds. I note that Ancare also had some sensitivity about matters such as packaging and size of packets and so on but to the extent of controls and other matters that ERMA is particularly concerned with, they would not be covered by the confidentiality clause.

It is then not automatic that anything an applicant asks for will be confidential. That the authority must exercise its own discretion and even once it has decided, under 57(1), that the information supplied does meet the test of section 9(2)(b), an applicant, another person can seek that information under the Official Information Act. The applicant then has an opportunity to defend its position but again it is the discretion of ERMA. ERMA need not accept the applicant's reasons as being sufficient and may release nonetheless.

McGRATH J:

So section 57 only applies for a time at a particular point, at the public notification.

MS AIKMAN QC:

It applies, yes, until the application is – if it's approved and then one comes to the controls and they must be made public so it is a temporal matter and it

does reflect, not only the Trips obligations but also just the general public policy that those who have developed a product are entitled to have a period where they can the thing to market without competitors stealing a march on them and that is something that nothing in the Official Information Act recognises but is clearly recognised in the Agricultural Compounds legislation as well.

McGRATH J:

And is ERMA's decision is subject to challenges to the Ombudsman?

MS AIKMAN QC:

It is subject to challenge to the Ombudsman. In fact that was the case in this case and –

ELIAS CJ:

That's under the Official Information Act as a matter of general application?

MS AIKMAN QC:

Yes, yes.

ELIAS CJ:

It's not in the scheme of this Act?

MS AIKMAN QC:

No.

ELIAS CJ:

Although I suppose the indication of the Act.

MS AIKMAN QC:

Yes.

ELIAS CJ:

Yes, thank you.

MS AIKMAN QC:

But I mean the – and presumably could both the decision of ERMA and the decision of the Ombudsman could have been subject to judicial review. That's not –

McGRATH J:

But essentially this whole, as the Chief Justice says, it's the Official Information Act regime applies and ERMA is like any other public body that makes an initial decision which is subject to the normal processes of review under the Act and under the law thereafter.

MS AIKMAN QC:

Indeed and section 57 to some extent parallels the first stage of that process.

McGRATH J:

So it's in those special position, ERMA, it's only special to the extent that the statute specifies particular consideration.

MS AIKMAN QC:

That's correct.

McGRATH J:

Yes, now it's just a deed but it looks as though largely it's in the realm of the Official Information Act and that balancing test that's applied.

MS AIKMAN QC:

Mmm.

WILSON J:

Section 57(1) directed to the point of public notification whereas 57(2) is a general application?

MS AIKMAN QC:

Yes, yes.

ANDERSON J:

Subsection (1) is rather more precautionary isn't it? It's where there's a possibility that it might be then it's withheld at that point?

MS AIKMAN QC:

Yes and then there maybe a review if somebody, if somebody seeks it and –

ANDERSON J:

But after that it's the O Y regime.

MS AIKMAN QC:

And as we've seen from one of the ones that Mr Brown took you to, at that point the applicant decided not to maintain the confidentiality and indeed that is what happened with Ancare although in somewhat unusual circumstances.

The select committee report which I've taken you to shows that the two pieces of legislation, the Agricultural Compounds Act and ERMA were very much seen as a package although they were enacted sequentially and sections 55(4)(a) and (b) recognised special protection of innovative compounds and those were the ones that were enacted as a result of the Agricultural Compounds Act. The effect of that is to give a period of five years' protection but it finishes at the point where a product is approved under the Agricultural Compounds Act. Now I understand I've had a discussion at the morning tea break with counsel for the New Zealand Food Safety Authority. The two Acts don't operate in tandem quite as neatly as one would like to think and it's sometimes – I had read it hat people would, and I think the legislation contemplates, that people first make an application under HSNO Act and then having been approved for that they would then go to the Agricultural Compounds Act. In fact that doesn't always happen. Even where a HSNO application is required and people sometimes go straight to the Agricultural Compounds Act and there is a risk of the director-general making a different

decision, apparently, from ERMA. However, I think the Court has to look at the legislative scheme and see that at least that contemplated that the two would work fairly closely together and indeed there is provision in the Act for reference between the two bodies where appropriate.

The important thing to stress is that the protection is only one of a limited time phase and that –

ELIAS CJ:

What is the point of it then? What could be the purpose of it if one is trying to think purposively?

MS AIKMAN QC:

Well one, not all applications will be approved.

ELIAS CJ:

Yes.

MS AIKMAN QC:

If it's declined the applicant may wish to go back again and reformulate the proposal. The applicant doesn't want all its technical information made available to its competitors at that point. There is no risk to the public at that point. It's not on the market. But even if it is ultimately accepted there will, there will be a time lag between the time when it is approved and it goes to market. Those are the times when it becomes public. There is certainly a degree of – and I think it probably arises more in relation to some of the genetically engineered organisms and substances where people may have particular concerns and there certainly is an element of the public having to trust the integrity of the processes of ERMA to get it right, that the ENR reports are thorough, the scientists have done their job and one can argue whether that's –

ELIAS CJ:

Where do you get that though, from the statute? That slightly paternalistic approach. What is there in the statute which after all provides for public participation which suggests that there needs to be that, that there is that element of trust?

MS AIKMAN QC:

I think the existence of section 57 or that one can keep some information confidential, that ERMA has the benefit of that, but not others, and that was clearly a matter that the select committee looked at quite closely in looking at that balance and Mr Brown included in his materials the debates from the first readings. I don't know that they were particularly helpful in that regard but there clearly was an awareness of that balance between public participation and the need, again on public policy grounds, that pharmaceutical companies and others could protect their information.

McGRATH J:

What's the provision for natural justice in here, the fair treatment provision is it or something in the Act –

MS AIKMAN QC:

In the hearing process?

McGRATH J:

Yes.

MS AIKMAN QC:

Yes I think it's a very general one.

McGRATH J:

I'm just really wondering if – because what you're really saying is that section 57 qualifies that too, aren't you?

MS AIKMAN QC:

Yes I mean one can accept that the position of Wyeth for instance had it appeared before the hearing on the substantive matter, was significantly prejudiced in not knowing what the compounds were.

McGRATH J:

I'd just like to see the provisions again –

BLANCHARD J:

Section 61(7) might be the one that you're thinking of. Establish a procedure that's appropriate and fair in the circumstances.

MS AIKMAN QC:

Yes.

McGRATH J:

Thank you.

MS AIKMAN QC:

And again one can perhaps draw some parallels between other Court processes. We're somewhat unusually but it is possible that information is confidential to the body and not to all the participants.

McGRATH J:

Well appropriateness and what's appropriate and fair in the circumstances, ERMA's going to take account in deciding how it balances public interest as against private interest in section 57 so the two must work together.

MS AIKMAN QC:

Indeed.

ELIAS CJ:

I'm not sure that the qualification of natural justice in subsection (7) is the full answer though because subsection (8) envisages participation by those who

have given notice they want to be heard, so there must be a wider concept of natural justice here than the procedure that ERMA chooses to adopt in a particular case.

MS AIKMAN QC:

There is but I think also there is the – if an application, sorry. If an objector came along and said, we are distinctly prejudiced in this hearing because we don't know what the substance is, that comes down to ERMA's discretion in terms of whether it should approve this substance or not. It might revisit the decision to withhold the information or it might decide that there is undue, uncertainty and that of course is one of the things it must look at when deciding whether to approve a substance or not so if it believed that there was merit in this objection, and that might particularly apply where there are substances which have never been approved before, genetically modified organisms or something, perhaps it would apply less so in a situation such as this one where you have four components that have already individually been approved and it's just the particular combination. It's what percentage of each that is being protected, ERMA might quite reasonably say, well, there is very little uncertainty in this case, we will approve it and obviously its decision is capable of review. But that's addressing another – it's not addressing what should go on the section 20 register, it's addressing the reasonableness of ERMA's decision in withholding information which is a quite separate issue from the one that the Court has framed. But I think it's relevant to the extent that there are controls. ERMA, although it would appear to have quite a bit of control over the process, it's not omnipotent. It is subject to natural justice, to reasonable decision making processes.

WILSON J:

Isn't there quite a direct relevance in that there would be in point in having the provision in section 51 directed to public notification if the relevant information had to be on the register? In other words if it has to be on the register, there's no purpose in limiting its public notification.

MS AIKMAN QC:

Indeed and – I mean there is actually quite a bit of public notification. There's the notice in the newspapers. There's notice given to all interested parties and there is a list of interested parties in the material and you'll see that that's quite broad. Government departments, competitors and others so most of those who are likely to make submissions will have received notification other than through the register. It's really a – for that purpose it's very much as a backstop rather than as –

ELIAS CJ:

But the point that's being put to you is that requiring notification on the register would undermine section 57(1).

MS AIKMAN QC:

Yes, yes.

ELIAS CJ:

Section 57(1) however is limited in terms of the public notification. It's to make sure, surely, that the information doesn't go out in a precipitate way but that the applicant will have the opportunity to make out the case at a later stage. I'm not sure that it really impacts on the natural justice point but I'm not sure that that's before us. All right we'll take the lunch adjournment now, thank you.

COURT ADJOURNS: 1.06 PM

COURT RESUMES: 2.18 PM

MS AIKMAN QC:

Your Honours, before lunch I indicated that there had been some discussion with representatives of New Zealand Food Safety Authority who were present in Court about the overlap between their legislation, the Agricultural Compounds and Veterinary Medicines Act and ERMA and I think it is perhaps useful if I actually take you to those provisions, so that there is no ground for

confusion. There are two extracts of that Act in my authorities at tab 2, however I will refer to a number of sections which are not included in that and I'm sorry, I don't have full copies of that but if you could bear with me with that.

The position as I understand it, is that applicants may in some cases make applications first to the Director-General under the ACVMA but that if it does involve a hazardous substance, it cannot be approved until it had been considered by ERMA. The relevant provisions of the ACVMA, section 9 which is not in your materials, just simply saying any person may make an application to the Director-General to register a trade name product. There is then section 12 which mirrors section 57 of ERMA and that is in the materials, where the Director-General may withhold information on the same grounds as section 9(2)(b) of the Official Information Act. Then section 13 which is not in your materials, the process of notification of the minister and departments and section 14, where there is a Gazette notice of the application and where, "The Director-General must publish a notice in the Gazette and give such further notice of the application as a the Director-General thinks fit, having regard to the nature of the application and persons likely to have an interest" and it includes a brief summary of the relevant information.

Now, I'm told orally by the Food Standards Authority that that regularly does include information of the active ingredients of the compound sought. However, it statutorily need not do so because section 12 obviously provides for some protection of information in some situations.

ELIAS CJ:

So, does that mean that the practice is not aligned?

MS AIKMAN QC:

Well, it may well be that at that stage, if people have been through the ERMA stage, that they are no longer concerned to protect the information, or it may be that they're just bowing to practice and I'm not in a position to take that any further. If Your Honours wanted further information on that, it might be appropriate to actually seek the information directly from the –

ELIAS CJ:

I'm not so sure that it really matters very much, does it Ms Aikman. I did think that in terms of your submission that the related legislation was helpful, that it's really quite different legislation and it doesn't provide for a consent process with public participation which is what we have in the case of the hazardous substances.

MS AIKMAN QC:

It does provide for submissions, it doesn't provide for the same hearing process. So, the Director-General will receive submissions in writing –

ELIAS CJ:

Does the Director-General have to notify the applications?

MS AIKMAN QC:

Yes.

ELIAS CJ:

Oh right.

MS AIKMAN QC:

Under section 14 there is a Gazette notice.

ELIAS CJ:

Yes.

MS AIKMAN QC:

My understanding is that that regularly contains more information than is the norm under an ERMA application. That may of course come later in time, so if ERMA has made its decision then there is no longer any sensitivity about the materials, unless they are, unless it is an innovative compound which I'm told applies to only a few of the agricultural compounds. So, there is a public process, there is a possibility of suppressing information under that Act and then a decision is made. Then we come to section, significantly section 21 of

the Agricultural Compounds Act, section 21(5) states that, "Where a trade name product contains an agricultural compound that is also a hazardous substance or new organism, the Director-General must not register that product under this section unless approval for that substance or organism has been issued by the HSNO Act."

To that extent, the two must work in tandem. Even if you applied to one before the other, you could not get registration under the Agricultural Compounds Act if you have a hazardous substance, unless it's been through that process.

McGRATH J:

So that was section 21, was it?

MS AIKMAN QC:

Section 21(5) of the Agricultural Compounds Act. Then, one comes finally to section 24 which again is in your materials which is a register of agricultural compounds. Section 24(1), "The Director-General must keep a register of all registered trade name products registered under section 21." So it doesn't come into play until the approval has been given. So at that stage, approval will have been given under the ERMA process and by the Director-General of Agricultural and at that stage it's probably not contested that the materials, that the substances are publicly available. So although they operate somewhat differently and there does tend to be greater disclosure under the Agricultural Compounds Act, they're nonetheless are not in conflict.

The tenor of my submissions before lunch and my written submissions, is that if one were to have an expansive definition of section 20 and the register provided for there, that it would simply be inconsistent with the legislative intent of the Act as a whole. I've also referred to the companion legislation but also inconsistent with the Official Information Act which of course works as an umbrella over ERMA being one of the organisations covered by the Act and by way of analogy, the Privacy Act, privacy considerations are unlikely to arise directly in relation to such applications but it has a similar balancing regime. It

is well recognised that commercial information can be subject of confidentiality provisions and I refer in my written submissions to a recent article by *Gunasekara, G [2008] "Privacy Rights For Companies" NZLJ 30* in the Law Journal regarding official information in companies in general. I've also referred in my written submissions to a recent Law Commission report on registers and again the primary focus of that report is their privacy reference but it does have relevance in this case as well. They attempt to define what a register means and it is quite clear from that that just because a register is designated as being a public register, it does not mean that everything on it is necessarily public. The Commission refers to it being public in whole or in part or to a degree of public access and one can think of examples such as for instance, the Births, Deaths and Marriages register, generally public but in some cases for things like adoption and things, one has to have special authority to go behind the register. The electoral rolls are another example, generally public but one can have a confidential part to it.

So, they come down with the conclusion that really the defining characteristic of a register is a roll or a list. It doesn't have any broader general definition in there and it's very much subject to its own legislation. In my submission, the appellants in this case confuse the purpose of a register as a list, with access to information under the Act and that if indeed information has been wrongly withheld by the applicant, by ERMA itself, or the decision of the Ombudsman is wrong, then judicial review is a more appropriate process for dealing with that decision of where the balance lies, rather than what is essentially a backdoor way of getting that information through a register.

Your Honours, those are my submissions. Unless you have any particular questions arising?

ELIAS CJ:

Thank you Ms Aikman. Thank you Mr Goddard.

MR GODDARD QC:

I think there probably are a handful of things on which I maybe able to provide some assistance. To begin with, perhaps I can just refer the Court to a couple of provisions that shed light on what is meant by substance in the Act and what that means for the need for approval for different compounds involving perhaps the same active ingredient. The short point, the end point of this submission, is that a new approval is required for any new mixture or compound even of familiar old ingredients and that I think is most apparent from the definition of substance in section 2, subsection (1) to which my learned friend Mr Brown referred the Court which includes in paragraph (c) any mixtures or combinations of any of the above and also importantly subsection (2) of section 2 which provides that for the purposes of paragraph (a) of the definition of the term substance, the definition of any mixture of elements or mixture of compounds may include a range of percentages of the elements or compounds making up the substance. So one can specify a detailed mixture with very specific percentages or have a range which will be one substance but if one has a different compound from one in respect of which there is an existing approval, either because there's a detailed approval and it's just slightly different, or because there's a range specified in an approval but one is outside that range then it's necessary to get a new approval.

That then I think highlights an important point about what is meant by a compound that should not be overlooked and that is that a compound of the kind we're talking about and MEP 600 is an example of this, will include one or more active ingredients, an active or the actives but also other components which are usually referred to as excipients or co-formulants and when we talk about the composition of a substance that's a reference not just to the actives or the active, it's a single one but also to all the excipients included in the substance. That's important because many agricultural compounds involve familiar old chemistry actives but which are combined in new and innovative ways with co-formulants which ensure greater ethicacy for example, to overcome resistance which otherwise develops in relation to parasites, like the worms at which this drench is directed.

So, there's a lot of innovative, a lot of science in the combination of one or more actives with one or more excipients and the question approved by the Court in granting leave to appeal which is in volume 1 under tab 2, is whether the authorities required to include on its register of applications details of the composition and active ingredients of the substances. So as I understand the issue before the Court, it raises the question not only of whether the actives must be disclosed but also of whether the composition as a whole must be disclosed and that is the question to which the appellant submits an affirmative answer should be given and that's, in my submission, a very ambition submission. I'll explain –

ELIAS CJ:

What's the answer if it's only the hazardous substance that has to be disclosed?

MR GODDARD QC:

Only the –

ELIAS CJ:

Hazardous?

MR GODDARD QC:

– components that are hazardous.

ELIAS CJ:

Is it (c) and (d)?

MR GODDARD QC:

It might – the answer in my submission is still that that's not required to be included on the section 20 register and that relates in part to the whole question of what the register is for and what it's not for, the very important purpose of the question raised by His Honour Justice Anderson earlier today. Before I come to that, I'm not going to go through my written submission in

detail but I should perhaps just flag that there is a very detailed description of the application process under the Act in paragraphs 8 to 33 of my written submission. The process is traced from receipt of an application under section 28 which includes extensive information, entry on the register under section 20, public notification under section 53, consideration of the application under part 5.

There are a couple of provisions which I should perhaps draw the Court's attention to because they haven't been referred to so far. In terms of the public notification process, that begins at section 53 and as my learned friends have noted, among the applications that must be publicly notified are section 28 applications. The method of public notification on which there's been consultation dealt with in 53A –

ELIAS CJ:

What is the application which according to the section 53(1)(a) must be notified publicly?

MR GODDARD QC:

The fact of an application is what has to be notified in accordance with the methodology for public notification approved under section 53A which involves a mix, as I understand it, of publication of certain details in newspapers and provision of more extensive information either on request to the Authority or through its website.

ELIAS CJ:

What does section 53A(3) mean, "Must publicly notify the method it proposes to determine"?

MR GODDARD QC:

The Authority is required to give public notice, presumably not necessarily using that methodology because it's a boots strap concept and that, of the method it proposes to adopt for notifying applications. In other words, there's to be consultation –

ELIAS CJ:

Oh, yes.

MR GODDARD QC:

– on how the public notification process will work for applications in the future. Submissions are received on that and then under subsection –

ELIAS CJ:

It's not in respect of specific ones?

MR GODDARD QC:

No, Your Honour, exactly –

ELIAS CJ:

I see, it's a process –

MR GODDARD QC:

– firstly its consulted about methodology, having settled the methodology it must then be applied.

McGRATH J:

Is it really the reference to the methodology in section 53A that indicates that section 53 is not actually requiring an advertisement containing the whole of the application?

MR GODDARD QC:

That's exactly right Your Honour and indeed is deliberately not expressing a view on how that notification will work because –

ELIAS CJ:

It's an odd use of methodology?

MR GODDARD QC:

Process would be a less pretentious term for the same thing.

ELIAS CJ:

Well, a method of public notification, that seems to be about the manner of public notification?

MR GODDARD QC:

Yes and in circumstances where there's a great deal of information in an application, I think the question that is assumed there is how much do you make available, in what manner, at what time and what this deals with is the extent of information that would go in newspapers to provide a headline about what's happening and then how you drill down to get more information.

ELIAS CJ:

Do we have this method?

MR GODDARD QC:

Not in the materials before the Court. I could arrange to have it made available.

ELIAS CJ:

No, I'd just really like to know that it does include what is to be notified, as opposed to that it will be advertised once in a daily newspaper circulating throughout New Zealand or something like that. Like the old High Court rules, I mean they're probably still the current High Court rules.

MR GODDARD QC:

I don't know myself Your Honour. I'll consult with my learned junior in a moment.

BLANCHARD J:

The definition of public notice might help.

ELIAS CJ:

Where's that, in the definitions, another definition is it?

BLANCHARD J:

Mmm.

MR GODDARD QC:

I'm grateful to Your Honour, a method determined under section 53A, or in the absence of a 53A methodology or where public notice must be given of something which isn't an application, for example the proposed methodology under 53A, by publishing a notice in one or more daily newspapers in the main metropolitan areas.

ELIAS CJ:

Well B though does look as if it is that sort of mechanical thing, the default position is not to do with what has to be advertised, it remains the application.

MR GODDARD QC:

Well it's the – the requirement is to publicly notify the application rather than to advertise the application.

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ELIAS CJ:

Yes, yes, that's the methodology, advertisement.

MR GODDARD QC:

But I think to notify it is to identify the fact that it's happened rather than to publish it in full. The full application is a very voluminous thing.

ELIAS CJ:

Yes, yes.

MR GODDARD QC:

The process, I think rather than speculating about what's been approved under 53A it will be better if I ascertain that at some stage and perhaps –

ELIAS CJ:

Well it's not necessarily determinative.

McGRATH J:

Whatever, section 57(1) anyway provides authority for withholding, doesn't it, from the public notification?

MR GODDARD QC:

That's what I was coming to Your Honour. Which is at the point where public notification takes place, the authority is actually directed, it's a mandatory obligation, to refrain from releasing any information supplied to the authority in respect of any application which may be able to be withheld under section 9(2)(b) so it's mandatory and it's very broad and importantly in terms of the link into the natural justice issues that Your Honour was asking about earlier, section 56 hasn't been referred to so far but that makes it explicit that the authority can consider, in reaching a decision under the Act, information which has been withheld under the Official Information Act.

McGRATH J:

Yes.

MR GODDARD QC:

And so Your Honour is asking about the, here I used paternalistic, elements of this, the extent to which ERMA was - we have seen this –

ELIAS CJ:

Well it's almost the dishonest aspect. If it suggests a process in which the public can participate but the public aren't informed of the critical nature of the nature of the application.

MR GODDARD QC:

I think that it's important to bear in mind what a submitter will and will not have and I touch on this in paragraphs 23 and 24 of my written submissions. As I say, the process of deciding whether or not to approve a substance for release involves as a first step classifying the hazard properties of the substance in terms of the international hazard criteria. And what a submitter

won't be able to do, in the absence of information about chemical composition, is make a submission on the correctness of that first technical step, identifying the hazard properties. That's what I note at 23 but that's the subject of an independent and rigorous scientific review by the staff of the authority but then importantly at 24, even in the absence of that information, submitters do have that classification as put forward by the applicant and as reviewed by ERMA, and information, this is all the information in my 24, the intended uses of the substance for its life cycle, particulars of the default controls and additional controls imposed and the assessment of costs and benefits and the independent assessment of those by ERMA in the evaluation and review report. So for example when it comes to making submissions about how compounds with a certain level of eco-toxicity should be stored or transported or handled, the public is able to participate. At most when one, and in relation to appropriate controls for the given level of toxicity or eco-toxicity, the public is able to participate. Is the public able to participate in relation to that initial step of considering whether a correct scientific assessment has been made of whether these chemicals in this combination have these particular hazard properties, no. Where that information is withheld that won't be possible.

McGRATH J:

But the decision to withhold itself is a balancing which must bring to bear, I'm sorry am I anticipating your point?

MR GODDARD QC:

Your Honour is exactly right. So my learned friend Mr Brown referred to the happenstance of whether a code name was used or not but of course this is not happenstance because all that information must be provided to ERMA for it to be able to consider the application and in deciding whether or not to release it, ERMA is required, initially, to adopt a precautionary approach, 57(1), but on request to apply the Official Information Act regime which requires first of all identification of whether the grounds for withholding exist, and the relevant provision 9(2)(b) is identified, and then of course the balancing that is required under section 9 because section 9 is not a bright

line release withhold test. It requires, first of all, that there be certain grounds which might justify withholding but then an evaluation of whether, nonetheless, it's in the public interest to disclose it, a public interest which includes –

ELIAS CJ:

There's a reasonableness indication isn't there, in section 9? Or is it in –

MR GODDARD QC:

I think it's whether there are –

ELIAS CJ:

– in this legislation? One of them?

McGRATH J:

Yes, the natural justice provision.

MR GODDARD QC:

I think the reasonableness provision that Your Honour is referring to is 61(7) a procedure that's appropriate and fair in the circumstances, I don't think the language of reasonableness is used in section 9 –

WILSON J:

Yes, 9(2)(b)(ii), "Would be likely unreasonably to prejudice the commercial position of the person who supplied … the information."

MR GODDARD QC:

Yes Your Honour is exactly right. And what I was thinking of was subsection (1) of section 9 of the Official Information Act which provides that, "Where this section applies, good reason for withholding official information exists, for the purpose of s5 of this Act, unless, in the circumstances of the particular case, the withholding of that information is outweighed by other considerations which render it desirable, in the public interest, to make that information available." So there's a very nuanced balancing regime involving initially a

precautionary approach to release and then an assessment under section 9 which is designed to accommodate the various public interest factors that are relevant and the basic submission of the Authority is that section 20 is not an un-nuanced elephant that comes tromping across the middle of that, mandating disclosure in circumstances where the section 9 balancing act would otherwise produce a different result and there are a few other pointers to that which I'll come to in a moment.

ELIAS CJ:

What is reasonable however or what is unreasonable must be contextual and it must fall to be applied in the circumstances of this legislation.

MR GODDARD QC:

Absolutely Your Honour.

ELIAS CJ:

Because on your submission, as you've acknowledged, there is an alsatia in terms of the participation. You cannot participate in respect of the –

MR GODDARD QC:

Sub questions.

ELIAS CJ:

Yes.

MR GODDARD QC:

In particular the correctness of the classification of the hazard properties.

ELIAS CJ:

Whereas another way of looking at it would be that there'd have to be very strong grounds for saying that it's reasonable to withhold that and to den you the apparent statutory opportunity to participate.

MR GODDARD QC:

Well two things about that. the first is that Your Honour's question assumes that there's not a blanket requirement in section 20 to release all that information but rather that a balancing occurs and that is consistent with the submission the Authority makes in these proceedings. That it's got the statutory obligation on consider requests for information and apply the statutory criteria. The question of how that balance should be struck is not one that's before this Court on this appeal.

ELIAS CJ:

No I understand that.

MR GODDARD QC:

And the primary method of challenging decisions of that kind by the authority is of course to seek review by the Ombudsman, as was done in this case, but the Official Information Act does contemplate that after that recourse has been adopted it is open to seek judicial review.

ELIAS CJ:

But there is a prior question as to whether, which again is probably not before us, but as to whether section 53(1) doesn't, which is in unequivocal terms, doesn't, requires identification of a substance before you've got a public notification of the application.

MR GODDARD QC:

And that there will be some information which may be material to the Authority's decision which is not publicly notified under 53 is explicit in section 56.

ELIAS CJ:

Yes.

MR GODDARD QC:

So then one simply is asking what that information –

ELIAS CJ:

I'm not troubled about additional information or supporting information or anything like that. I'm troubled about the non-identification of the whole reason why application is necessary.

MR GODDARD QC:

I think that's an issue which arises on a case by case basis in the application of part 5 rather than in interpreting section 20 although those have to be read together. In that sense I don't know that it need be addressed and perhaps it might be a little dangerous to address it circumstances that it hasn't been the subject of submissions by all counsel. There are –

BLANCHARD J:

Well here there was an OIA challenge wasn't there?

MR GODDARD QC:

There was Your Honour and the Ombudsman –

BLANCHARD J:

And it's gone no further than that?

MR GODDARD QC:

Yes. and in those circumstances I think it wouldn't be appropriate for this to become by the back door as it were a challenge –

ELIAS CJ:

I'm just concerned we shouldn't –

MR GODDARD QC:

– to the correctness of the –

ELIAS CJ:

– overstate, even if we agree with you, on the section 20 point. That we shouldn't indicate any wider proposition and I remain troubled by section 53(1) and whether you've really got a notification of an application if you don't identify the essential – or don't sufficiently identify the substance, the substance which requires the consent in the first place.

MR GODDARD QC:

That's where one comes to a difficult balance which this legislation seeks to achieve between openness and public participation on the one hand but also the economic incentives that are created by confidentiality in respect of new products and their uses and there is a real issue about the extent to which, if disclosure in New Zealand in relation to composition is greater than disclosure required elsewhere, products will be brought to New Zealand because otherwise this will be an opportunity to gain information which can be used in other jurisdictions where disclosure is otherwise more restrictive, and if one thinks for example – in that, nothing's addressed to applications of this kind. More generally in relation to my friend's submission that the section 20 register has to include active ingredients and indeed the composition of a substance, one would get some quite surprising results in relation to applications. For example, under section 31, to bring substances into New Zealand in containment to be kept in laboratories for the purpose of research and development. If it was necessary to disclose all the details of any substance that was brought into New Zealand for research and development in a laboratory, even though that wasn't going to be publically released, and even though there's no public notification obligation in respect of such applications, that would have very dramatic implications for the ability of New Zealand firms to carry on research and development here and it would –

WILSON J:

Sorry, isn't again at least a partial answer to the point the Chief Justice is putting to you, the point that I sought to put to Mr Brown this morning, namely that the Authority at paragraph of this policy at page 186 by stating that the

information available to the public must be sufficient to make it clear what the application is for, what are the likely risks, costs and benefits and what effects the hazardous substance or new organism may have, is really going some way to meeting that point?

MR GODDARD QC:

Yes Your Honour and that reflects the Authority's understanding of how it should strike that balance when applying these provisions.

McGRATH J:

It also reflects the mandatory obligation of the Authority to have a procedure that's appropriate and fair in the circumstances. I mean the balance must end up with something that is appropriate and fair in the circumstances or the Authority will be outside its jurisdiction.

MR GODDARD QC:

Exactly Your Honour but at the same time that, and it's simultaneously of course, one of the factors the Authority has to bear in mind in developing that policy is legitimate concerns about confidentiality on the part of applicants and the legitimate protection of those claims to confidentiality in the interests of access to these substances in New Zealand and the continued conduct of certain activities.

ANDERSON J:

Can only bring that into account when it's administering the Official Information Act because in as much as the identity is part of the application, you get that from an analysis of what the application must contain, the default position is total disclosure under section 53 and it's only when section 57 comes in that the default position is altered and under section 57 is the precautionary step if it might, there's a sort of temporary withholding, sort of interim injunction type thing, and after that it then moves on eventually to a process of Official Information Act analysis and resolution.

MR GODDARD QC:

Your Honour is exactly right. so the default position is that everything must be publicly available unless 57(1) requires a provision withholding because it may be confidential in which case a request for that information may follow and at that time the Authority must apply subsections (2) and following of section 57. Your Honour Justice McGrath I think asked earlier, I think it was Your Honour, whether it was pure Official Information Act or whether there were any special provisions in this Act and there are just a couple of respects in which there are additional rules over and above the normal Official Information regime. The first of course is the precautionary withholding under subsection (1) to enable the issue to be considered properly. The second is the notification obligation under subsection (2). That's good practice under the Official Information Act but the Official Information Act doesn't require that the person who provided information be notified and have a specified amount of time to respond before a decision is made. So the potential for real confidentiality concerns to arise and the desirability that the provider of the information have an opportunity to comment, is built into this Act in a way that it's not in relation to the Official Information Act generally, suggesting a special sensitivity about the information here.

ANDERSON J:

Now the practice of including alleged confidential material in an appendix is really just an administrative mechanism for bringing the matter to the attention of ERMA.

MR GODDARD QC:

Exactly Your Honour. The other place where there are special provisions in relation to the Official Information Act is section 55 and that has a number of limbs which again I think it's important to notice in order to understand the balancing act, the real tightrope which this legislation requires the Authority to walk between public participation but also protection of confidentiality. The first is subsection (1) which contemplates the provision of information in advance of an application for the purpose of getting the Authority up to speed and explaining what might come along which provides that that information is

held on behalf of the person and the provisions of the Official Information Act don't apply to it, which of course is very unusual in terms of the structure of that Act, and what's more subsection (2) goes on to provide that that information shall be returned on request. So if someone decides not to proceed with an application, for example because after preliminary discussions with the Authority they are told what would need to be disclosed in New Zealand in order to pursue that application, they are entitled to get that information back and in what is otherwise a departure, I think, from the archives legislation and the Official Information Act, that information is treated as if it was never held by –

ANDERSON J:

Well it's not official information in effect.

MR GODDARD QC:

It never becomes official information which is an odd thing for information given to a Crown entity.

ELIAS CJ:

Well you have to have that so that – you have to have something like that because this is a public, this is amenable to the Official Information Act.

MR GODDARD QC:

It doesn't exist in many bodies though. If Your Honour considers the Commerce Commission, for example, I picked that simply because it's a crown entity whose workings I know well. There's nothing similar in that so if one makes a confidential approach to the Commerce Commission about a possible application that might be made, the Commission doesn't have the power to treat that as if it never had that information and treat it as if it's not official. This is a very special set of provisions.

ELIAS CJ:

Oh yes, I understand that it's a specific provision but it applies – so it carves it out of the Official Information Act.

MR GODDARD QC:

Yes.

ELIAS CJ:

But that is not what happens once you have an application.

MR GODDARD QC:

Oh no Your Honour. I'm simply illustrating that there are a number of years in which the Official Information Act is modified in its application – these applications, all of which are consistent with the idea that there are real values to the protection of confidentiality –

ELIAS CJ:

But aren't there two –

MR GODDARD QC:

– under the scheme.

ELIAS CJ:

- regimes that are in operation here. One is official information and this is a public agency which in the exception – in the absence of an exception would be amenable to the Official Information Act regime. That is not to be sufficient protection for the know-how and commercial interests of those involved here but then there is in parallel a system for approvals in which public participation is mandated and there is still an issue as to how you notify the application. Whether you can notify an application simply by using a cipher?

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MR GODDARD QC:

I'll come to that a little more directly in a moment. First of all, in my submission, the most important point is that that is not answered by section 20.

ELIAS CJ:

Well, that may well be right –

MR GODDARD QC:

In which case, the issue before this Court I think is dealt with and Your Honour may wish to be cautious about how much further the Court goes but second, I would submit that there are circumstances in which the balance can tip towards disclosure and indeed that this Court has to assume that that would be the outcome, potentially in some cases on this appeal because that's what really gives rise to the important practical issue before the Court.

Coming back to 55, after subsections (1) and (2), the pre-application stage, there are then some provisions which are relevant after applications have been made and I do just want to emphasise those. The relevant ones for the purposes of agricultural compounds are subsections (4)(a) and (4)(b) which give rise to the, give effect sorry, to the trips obligations that my learned friend Ms Aikman referred to. Although that's not applicable here, again, whatever the Court decides in relation to section 20 must work of course for applications where the active ingredient is an innovative agricultural compound. Subsection (4)(a) provides that, "Where any information is held by the Authority relating to an application made under this Act in respect of a hazardous substance and the substance is the subject of application is also the subject of an innovative agricultural compound application as defined in part 6 and that information includes trades secrets or information that has commercial value that would be or would be likely to be diminished by disclosure, the provisions of part 6 of that Act, or the modifications, apply to that information as if the information were confidential supporting information as to find in that part of that Act." So that's any information held in relation to the application must be treated as if it were confidential supporting information as defined in that Act.

If one looks at confidential supporting information, the definition of that in the Agricultural Compounds and Veterinary Medicines Act, this is included in the extract under tab 2 of my learned friend Ms Aikman's authorities. So that's

tab 2 of Ms Aikman's bundle, section 72 interpretation. Confidential information first of all, trade secrets and information that has commercial value that would be or would be likely to be diminished by disclosure and then confidential supporting information, means confidential information given in or in relation to an innovative agricultural compound application. So it's not just supporting information Your Honour, it's also information in the application.

McGRATH J:

Sorry, I lost you a bit, Ms Aikman's authorities tab 2 did you say?

MR GODDARD QC:

Tab 2, section 72, interpretation, it's the second to last page of the extract –

McGRATH J:

Thank you.

MR GODDARD QC:

– definition of confidential supporting information. That's confidential information, if information has commercial value likely to diminish by disclosure in or in relation to an application. Now –

ELIAS CJ:

Although the heading is "Confidential supporting information." That's what is defined and it may be given in an application or in relation to it?

MR GODDARD QC:

But the question –

BLANCHARD J:

Or about the confidential agricultural compound –

MR GODDARD QC:

– or about the compound.

ELIAS CJ:

Yes.

MR GODDARD QC:

In my submission, that can include the composition of the compound, the co-formulants that are included in it and even perhaps, or even some of the actives in it. So any of that can be confidential supporting information in relation to an application. There's no reason to read that down and there are strong reasons to read it in that way when one looks at the nature of the obligation of New Zealand under trips and again, if I could just take the Court to the one page copy, one page extract provided by my learned friend Ms Aikman.

My learned friend Mr Brown referred to supporting information, data sets about research into that but in fact there are two limbs to this protection and my learned friend rather skated over the first. Article 39(1) requires members to protect undisclosed information in accordance with paragraph 2 and data submitted to governments or government agencies in accordance with paragraph 3. Now paragraph 3 is test and other data, research trials and things like that but if we go back to 2 it's perfectly general, natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed or acquired or used by others without their consent in a manner contrary to honest commercial practices so long as such information secret has commercial value and has been subject to reasonable steps to keep it secret.

Now, there's no reason at all why that can't include composition of substances. My instructions are that claims to confidentiality are regularly made by reference to the scope of this article –

ELIAS CJ:

Do you say that this is not, this sort of case is not a case under paragraph 3 because it would seem to be?

MR GODDARD QC:

If it's not under 3, it's certainly under 2. My learned friend Mr Brown sought –

ELIAS CJ:

But if it's under 3, why would one go to 2?

MR GODDARD QC:

Mr Brown sought to distinguish between information about the substance itself and supporting information –

ELIAS CJ:

Yes.

MR GODDARD QC:

– and his submission was that it's only the supporting information that is protected by this regime. My submission is that that's not correct, that the regime includes, whether under 2 or 3, information about the composition of the compound itself but of course there are then safeguards in relation to the process because of the references to unreasonableness, the references to public safety which may require disclosure of some or all information and may require disclosure at certain times. For example, if one looks at the reference to, in paragraph 3, the obligation to protect such data against disclosure except where necessary to protect the public, one can see why one might have an obligation to protect it until the substance is marketed and made available to the public at which point, in the interest of public safety more disclosure is needed than it was earlier.

All I wanted to say really was, again, that there are important international obligations in relation to confidentiality of information concerned certain substances, not this one but others that are dealt with under the same regime, that there is a mechanism for dealing with those claims to confidentiality in section 55 which needs to be applied on its terms and that it would be odd in the extreme if the register provision in section 20 overrode the section 55 protections.

I'd like to come next to Your Honour Justice Anderson's question, so what is this register for and the question about whether you can take something that's sloshing round a field and check it out on the register? The answer is no and moreover, the register is not designed to be a register of all hazardous substances. That is most readily apparent if one notes that there are very many hazardous substances which do not appear on the register and there are two main pathways by which a hazardous substance can be imported into New Zealand or manufactured in New Zealand but not appear on the register at all. The first is under part 6A of the HSNO legislation group standards. Under part 6A "The Authority is empowered to issue, amend and revoke group standards for groups of hazardous substances which are of a similar type or have similar circumstances of use so the risks of the group hazardous substances can be effectively managed by one set of conditions." I reading from section 96A and very many hazardous substances are the subject of group standards and where a group standard is issued, what section 96E provides is that, in subsection (3), "That a hazardous substance to which 96B(2)(a) applies which is a group standard is deemed to have been approved by the Authority under section 29."

So if you import or manufacture a hazardous substance which falls within a group standard and you comply with the group standard, then there will be no reference to that on the section 20 register but it nonetheless can perfectly lawfully be imported into or manufactured in New Zealand. In addition to that and this is very important because it goes to what the purpose of this register is, so there are many, many hazardous substances which do not appear on the register at all by virtue of part 6A. In addition, when this legislation came into force there were many hazardous substances including quite a few drenches that had been being used in New Zealand for many, many years. They were the subject of a transitional regime under parts 11 to 16 of the legislation. Now, those parts have expired but included and section 152 provided for them to expire on a particular date which was eventually extended out to a date in 2006, they have now expired, 1 July 2006 I think.

What the expired provisions included was also a provision, section 152 which provides for expiry, provides in subsection (3)(b) that notices of transfer made under section 160A continue in force following the expiry of parts 11 to 16. When one goes to section 160A, what one sees is provision –

ELIAS CJ:

This has been repealed, hasn't it because mine, at least it's crossed out –

McGRATH J:

It's an expired provision –

MR GODDARD QC:

It's an expired –

ELIAS CJ:

It's expired, yes.

MR GODDARD QC:

– but it continues to have effect.

McGRATH J:

That's the 2006 reference?

MR GODDARD QC:

Yes, that's absolutely right Your Honour. So it expired in 2006 but the critical thing is that subsection (3)A of section 152 provided that notices of transfer made under section 160A continue in force following the expiry of these parts. So where certain actions have been taken under 160A that survives the expiry and when one looks at 160A what that provided was that the Authority may from time to time, I notice in the Gazette, issue a notice of transfer relating to a certain substance or group of substances. What that notice of transfer can do is provide that they are not longer subject to the provisions of part 11 to 16 and that is they come out of the transitional regime, deem them to be have

been assessed and approved under section 29 and deem them to have certain hazard classifications.

ELIAS CJ:

What are they, they're just 1, 2, 3, 4, 5?

MR GODDARD QC:

Exactly, those numbered classifications for toxicity, eco-toxicity, explosiveness, all those other interesting properties that have that international classification regime.

My instructions are that there are some 10,000 hazardous substances which can lawfully be imported or manufactured in New Zealand pursuant to transfer notices, grand parenting provisions, that continue in force today. So many, many thousands of hazardous substances can lawfully be imported and manufactured because they're deemed to be approved despite the fact they're not on the register and that's not an historical anomaly because part 6A continues to provide for group standards which will result in the availability of hazardous substances which are not on the register. So the register is not intended to operate as a comprehensive register of hazardous substances and there is no expectation at all in this legislation that one can take a white plastic bottle that one comes across out in the field and trance that substance back to the register. Indeed, the odds are that you won't be able to.

The Court will have seen the approval numbers in those years, they're in the, you know, 10, 50 or 40 a year as compared with the many, many thousands that are subject to these generic deemed approvals. So the register is not a comprehensive register of hazardous substances. It's not designed to provide notification for the purpose of public hearings, there's a separate part of the Act with a separate balancing regime which is designed to do that. It's not designed to facilitate emergency response, there's a whole separate regime for that, built into the controls regime, in terms of access to information, the different timeframes within which different layers of information must be available and I deal with that in my submissions. That really drives one back

to Your Honour's question, so if it's not for all those things what is it for? I think I address that in my submissions at paragraphs 39 to 41. In short, this register is a register of applications considered but determined by ERMA New Zealand, it's not a register about hazardous substances, it's a register which provides information about ERMA's decision making process and where it's up to in relation to particular applications. That I think is apparent, both from a process of elimination and also from its location in the statute. In my submission it's no accident that the register provision is in part 4, the part that establishes the Authority and it's no accident that it includes all applications made to the Authority including ones which are not otherwise the subject of public notification. It's a record of what applications have been made to the Authority, whether they've been decided and if so whether they've been approved or rejected but it's not expected to be used for any of the other purposes which are an essential platform, from my learned friend's submission, that therefore there must be more in it.

There's nothing unusual about registers serving that sort of function. I think for example, again because of long familiarity with section 60 of the Commerce Act which requires the Commerce Commission to keep a register of applications made to it in respect of restrictive trade practices and the only function that register serves is to identify what applications have been received by the Commission and where they've got to in the decision making process. It's not a register of permitted restrictive trade –

ELIAS CJ:

It's an accountability tool.

MR GODDARD QC:

Exactly Your Honour and a ready reference to whether or something is still live or whether it's been decided, if it's been decided what the outcome of that was.

ANDERSON J:

The information that I envisage, is that it's not very extensive.

MR GODDARD QC:

Exactly Sir.

ANDERSON J:

ERMA's equivalent of national standards is it?

MR GODDARD QC:

I think I hesitate to risk a view on that one in something that's being transcribed and published on the internet Your Honour but yes, it's a very, it's a lowest common denominator of disclosure applicable to every type of application received by ERMA, including those which are not, for good reasons, the subject of any public notification or any public consultation and where the public needs richer information in order to participate in an application process or to respond to safety risks, the legislation has separate carefully designed regimes for providing –

ANDERSON J:

Where is the hazard response section, or regime?

MR GODDARD QC:

The hazard response regime is provided for, the details are in regulations, the empowering provision is section 76. It's worth looking at that because if one looks at 76, "Requirements for containers, identification, disposal, emergencies, tracking and fireworks," it's very broad, empowering provision for regulations which do various things including, "(b) prescribing requirements for specifying the identification, labelling or advertising of hazardous substances" and in "(d) prescribing requirements to manage any emergency involving a hazardous substance" and there are screeds of regulations sitting behind this Act.

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Just on the question that the Court raised earlier today about what is the point of this, the definition of identification in section 2. I suspect that it was included for the purpose of this empowering provision. When one looks at

identification in section 2, it's defined extremely broadly to include provision of any information about a substance or organism which identifies its chemical or biological nature, specifies nature and degree or type of hazard, describes precautions to be taken, directly or indirectly aids in managing any hazardous effect, identifies and specifies the means of contacting any person knowledgeable in the management of the substance. So one has that very broad definition of identification, and then a power to make regulations prescribing requirements in relation to identification. So I think it links quite logically into that empowering provision. And what one then says, that links, in turn, to section 77 and following on controls on hazardous substances. Because the other thing that the Authority does when it grants an approval is determine what controls will be imposed on that substance. My learned friend Mr Brown quite rightly explained that these are critical conditions without which the risks would not be acceptable, and the substance could not be approved. There are default controls, which apply to particular types of hazard under the legislation, but the Authority can vary those, either by imposing additional controls or by disapplying default controls that are not applicable. And again, as my learned friend explained, one sees, both in the Evaluation and Review Report, and then in the decision itself, consideration by ERMA of what controls are appropriate. And those controls include specification of information that has to be provided in order to manage risk appropriately. And so, for example, my learned friends took the Court to the requirement under the identification regulations that certain information be provided about the MEP 600, itself the chemical details and concentration of two of the ingredients, ingredients A and C. So that's all picked up in that, that's the hazard management end.

ANDERSON J:

If the Board want another indication that it's not a hazard response mechanism, is that you can only search the register during office hours. And the hazard might arise outside of office hours.

MR GODDARD QC:

That's a much simpler path to what I was trying to say, Your Honour.

ANDERSON J:

The only problem I think, and I'll be grateful to you for your submission on this, is why should this quality control register, or performance register, require a sufficient description to uniquely identify? Because it can serve the quality control purposes without giving that.

MR GODDARD QC:

I think that that's best answered in two bites. The first part is, to echo McGrath's J comment earlier today, there's more literal force in the appellant's submission than there is purposive force. If one looked at that line in isolation, one might say that that's a lot of words to say "unique identifier". But those words have to be read in the statutory context, and in a way that makes sense against the backdrop of the other provisions. It can't be an elephant which charges.

ANDERSON J:

It gets back to the point, perhaps, that I raised earlier today, that you can have an identity without having a description of its components.

MR GODDARD QC:

That was the second limb to my answer, that in my submission, if one says which legal person is responsible for such and such, Fletcher Construction Limited, that actually is a sufficient description of the company to identify it. And one doesn't need to describe who its directors are, who its shareholders are, what business it's engaged in. The name alone is a sufficient identification of the company. Or Your Honour Blanchard J referred to Coca-Cola, and my submission, if you're asked, "What is in that glass?", and you're considering whether or not to drink it, and you're told, "Coca-Cola", you have a sufficient description to know what is in it, and perhaps to avoid it. Whereas if the response were "Ata Rangi celebre", for example, that's also a sufficient description, although it doesn't disclose which varietals of wine or anything like that are in the celebre blend, and might produce quite a different rational response to the contents of the glass.

ANDERSON J:

It does rather seem, I think, that the register is not meant to be completed progressively, but an entry is made after a disposition. And after a disposition, a question of whether information has been withheld or not will already have been decided. And so the identity will response to the degree of disclosure that's already been determined. So if there's no secrecy involved, it can be a very specific component-ridden description, or if there has been a withholding, it will be altered accordingly.

MR GODDARD QC:

That's exactly right, and that's where, perhaps, I think possibly the last point I wanted to deal with.

ANDERSON J:

ERMA determines, in accordance with section 20, what goes on the register?

MR GODDARD QC:

Yes, Your Honour.

ANDERSON J:

But not applicants –

MR GODDARD QC:

Yes, and ERMA will include any information that it considers properly to be included in the register in accordance with the statutory scheme. And an applicant cannot decide that, although possibly in the course of interacting with ERMA before an application is formally made, if advice is given that certain information will go on the register or be released, that might result in a withdrawal of the application and the non-availability of the product in New Zealand. Which is why a balancing mechanism is so important.

BLANCHARD J:

Mr Goddard, just as a matter of interest, although it's probably of no relevance. What is a project, as referred to in section 22(c)(a)

MR GODDARD QC:

I hope it's not relevant, Your Honour, because I have no idea.

BLANCHARD J:

There's a tendency in this Act for them to scatter words around. It's a bit like parts of the Act were drafted by committee which never met.

MR GODDARD QC:

It's not a beautiful Act.

BLANCHARD J:

Well, it's certainly far from the worst I've ever seen.

MR GODDARD QC:

But it's pretty horrible. Section 42(A), my learned junior tells me. "Rapid assessment of projects for low-risk genetic modification". So a project is one of those. So that's not a loose scattering, unlike, perhaps, words like "unique" and "unequivocal", which seem to have been used without – or "identify" and "identification", which are clearly used in very different senses in different places in this Act, in an extremely unhelpful way.

WILSON J:

There must be an obvious answer to this, but why isn't information about the compounds as intellectual property without any need for confidentiality?

MR GODDARD QC:

That will depend on whether the criteria, for example, for granting a patent, are met or not. And those criteria are not exactly the same as the commercial sensitivity criteria under the Official Information Act, and under this Act. So one might expect there to be an overlap between those products that are the

subject of patent protection, because they're new, non-obvious, and those which are the subject of some – but of course, one of the prices that one pays for obtaining a patent is disclosure of information. And that's not always seen as the most appropriate way of protecting confidential information. So this legislation also accommodates an alternative track of not patenting, but –

WILSON J:

If a particular product had been patented, it would be difficult to see why an application in respect of that product should attract confidentiality.

ANDERSON J:

You couldn't patent this, could you, because it's all known substances, just a combination of them.

MR GODDARD QC:

My understanding, and I am at risk of straying into areas that I'm not really very competent in, is that the way in which the different substances are combined can, in some circumstances, justify the grant of a patent, for example, the use of a particular active, where they knew, surfactant, in a way which is non-obvious. Mr Brown, who knows much more about this than I do, is giving me a slightly pitying look, which suggests I should stop.

1530

ANDERSON J:

It may depend on whether it actually results in a completely new entity?

MR GODDARD QC:

I think the better answer is, I don't know and again, I hope not relevant to the question.

WILSON J:

It makes me feel much better that you don't know.

ANDERSON J:

It isn't relevant.

MR GODDARD QC:

I'm really glad to hear that Your Honour. Let me just check that there's nothing else that I thought I could help on. Justice Blanchard's question about what the point was of withholding information that will need to be disclosed on labels eventually.

BLANCHARD J:

Is it to stop competitors catching up rather quickly?

MR GODDARD QC:

That's exactly right Your Honour and that's explained in the response of Ancare to the enquiry from the Authority about whether it had any objection to the release of the information in this case rather well in fact. In volume 2 of the case, under tab 12 which is the evaluation review report, there are a large number of annexures including the correspondence on this issue and at pages 175 to 177 there is an explanation from Ancare about why it seeks this confidentiality. Beginning on 175, third paragraph, "The number of common excipients, limited number of actives, trade secret" and then, "A certain amount of time, money and effort invested in development, release a request for information we've got an unfair advantage to the recipient, jeopardise the commercial position" and then over the page –

ELIAS CJ:

There's quite a lot of emphasis on trade secrets which is not pursued?

MR GODDARD QC:

Was not accept, that's right but perhaps – over explaining the market advantage, the opportunity that would be created, at the top of 176 there's then a, "Please explain why this prejudice would be unreasonable." There's a reference to the R&D budget of three million per annum, new developments, combination of listing molecules, not always obvious, exploiting a niche of the

market unidentified my competitors, release formulation ingredients so early in the development process that our competitors can identify this niche, realise the significance of new development, information competitors would not normally have like a product launch that allows a reasonable a timeframe to establish a market and a brand before competitors can follow, early access cuts the timeframe considerably, market segment worth 100 million per annum in New Zealand, a new product such as this could expect initially to sell one to two million per year, the claim is that is market advantage is lost, sales could be half that, it is therefore unreasonable. Now, that's the claim, whether or not it's justifies of course falls to –

ELIAS CJ:

It was quoted extensively in the Court of Appeal judgment, wasn't it?

MR GODDARD QC:

Yes.

ELIAS CJ:

So when you say whether or not it's justified, the Court of Appeal seems to have treated it as –

MR GODDARD QC:

It's a claim which could be made out in a particular case and if it were made out that would justify the withholding and that's all that's important for the purposes of this I think, rather than whether in this case it was or was not and so that's the answer to the conceptual question, why would it be justified but eventually if it had come to the point of public release, public safety can only be assured by the provision of certain information and that's why the controls say, when you come to distribute this the public must know that these ingredients are here, must know the names, must know the concentrations, that's an important part of the information for safe handling and response. Before that, there is no justification for undermining the commerciality sought to be protected, or at least there can be in the absence of it and that's all that matters.

Perhaps on that, I should just pick up one comment of my learned friend Ms Aikman. My learned friend suggested that once a decision has been made by ERMA there is no sensitivity at all in relation to the composition of a substance. That's not the position. There is often continuing sensitivity, right up to product launch which is the point at which two things happen. Firstly information, such as information about ingredients (a) and (c) will become available on labels but also of course, it becomes possible for a competitor to go out to the nearest RD1 store, buy a large white bottle of it, take it away to a lab and analyse what it contains. So beyond that point, it is difficult, depending on the substance, often impossible to maintain confidentiality in relation to composition or aspects of composition, there may still be confidentiality about other issues in relation to the substance but that is the point at which, as explained in that correspondence, it's accepted that in order to go market confidentiality will be either lost or substantially reduced. Right up to that point and certainly well beyond ERMA approval, potentially that confidentiality may be very material and that's why the decision continues to refer to ingredients (a) and (c) rather than including the names and the decision.

Unless there's anything else I can assist the Court with?

ELIAS CJ:

Thank you Mr Goddard. Mr Brown, do you have a reply?

MR BROWN QC:

There's only three matters I want to speak to. The first is this Official Information Act position that largely I think is the driver, or the point of departure of my learned friend's submission Mr Goddard which were wonderfully fulsome for someone assisting us. Having introduced it, he then came to section 9 and said there's no bright line and that's the whole point, there is a bright line here in relation to code names. Code names are a bright line, they are accepted, unless like Bomac, you elect to pull B, L, A, C, A, et cetera and give the details of the compound and he says that in the register

it's not a lowest common denominator. Well, what's the lowest common denominator? A code name is not even the lowest common denominator for a sufficient description of the substance, it simply can't be and it's not just a literal approach, with respect, to say there is no description or no sufficient description. You have to accept, with respect, that with that number there is no description, there is an identifier and the problem that I have with this, however you choose to describe section 57, Justice Wilson I think put it as reading on to section 20, is this, fine if one is prepared to say we won't have in a register a sufficient description of the substance because it's confidential. That's fine, I'd be happy to see a register that says either the sufficient description, or says no, zip, for the time being, until it's disclosed, there's nothing in the register. The problem I have, with respect, is a code name that both, as it were, achieves the confidentiality that is aspired to but masquerades as a sufficient description to provide the unique identification because that's what the Court of Appeal has held that it does and that's the problem that we have with the code name. It should either be a sufficient description because that's what the register requires, or it should be that the register is overridden by section 57 and there's nothing there but this code name which is just a, as the former affidavit said, a name invented by the applicant, sits in there and it really has the purpose of occupying that spot in the register –

McGRATH J:

We have to look also, don't we, at the statement of purpose for example and the other links that the register has –

MR BROWN QC:

Oh yes, absolutely –

McGRATH J:

– in considering sufficiency?

MR BROWN QC:

Yes, you do and they're all linked into sections and just to deal with that project question of Justice Blanchard. Actually the first and I think the fundamental reference to project is actually in section 40, subsection (2)(a)(ii). This is the containment approval for new organisms and it's the description of the project and the experimental procedures to be used and I refer to section 40 because at section 40, it's section 40 that has a list of those applications required to be publicly notified. You'll see section 40 listed in section 53(1)(d), an application under section 40 to field test a GMO and that's why project appears in the register because it's a feature of that particular application. They're all there for a reason.

Now, it may be that you're persuaded that it's of insufficient interest to a member of the public to go and look at these things, that it doesn't really matter, that it's some machinery proposition or the like but in my submission, a register can have many purposes. It may not be the best response to an emergency on Waitangi Day, although as it happens one of the advantages of the voluntary internet access means that it is available 24/7 if you can get to a computer but that's not actually authorised by the statute but my learned friend has put a lot of weight on that particular manifestation, how you can go through the windows to see the various documents that belie it.

ANDERSON J:

You can't interpret section 20 by reference to a practice that's developed administratively.

MR BROWN QC:

No, I agree, I agree but that was something that arose in earlier submissions. It just happens to be that it has in practice a greater utility than if we were to say well, if it's nine to five what's the point. I don't say it's the first point for an emergency but if you were in an emergency and you were having trouble finding information, you wouldn't expect someone to say well, don't look at the register, it's not there for that reason, if it's got the information, then it's useful and the controls and things of the like. So, I say that on the question that we

really ask the Court to say yes or no to, that is whether this code name, this construct, is a sufficient description. I say and we continue to say, it isn't and it doesn't actually help in terms of try to justify a code name to say that section 57 reads on to section 20 because the approach of integrity would say well, we'll just leave it there until the confidentiality has lapsed and then the name will appear but there's never been any suggestion at any stage that that is the way the register changes.

The second point I want to make is this and it is a, not a change but a clarification of our position in the light of the fact that my learned friend for ERMA, I forget quite the word he used, I think it was optimistic, describing our approach in relation to the approved ground and he went on at great length about compositions and excipients and formulation and the like. We seek very narrow matter and that is the hazardous substance and/or its actives and that was apparent from the form of application. It's most certainly apparent from our submissions at paragraph 71, "The approved question –

ELIAS CJ:

Sorry, the hazardous substance or?

MR BROWN QC:

Its actives, the things that are the, generating it, these excipients. If you take something like your aspirin or whatever, they're fill of –

BLANCHARD J:

I don't think you need to worry about this point. The grounds are not like cash dated questions.

MR BROWN QC:

Oh no, I really accept that but I was anxious about the, what we would – suggesting that we're trying to find out this composition, this, you know, what's really in here. What we're driving at is the hazard –

BLANCHARD J:

The active ingredient.

MR BROWN QC:

The active ingredient.

BLANCHARD J:

Yes, well that's very clear from your submissions.

MR BROWN QC:

Yes and that's what's not disclosed by the code name. That's what his submissions say in terms of that chart that says actives not disclosed. In practical terms, all we seek is what Bomac released in their one. The third point and it's not really for me to apologise to the Court for this but all this business about how the Food Safety Authority operates in terms of the AVMAC legislation has come before the Court in a rather untidy way and it's fair to say that those representing the Authority who only come to observe have been at pains to arm us all with the correct information because they felt I think that it wasn't being correctly conveyed. It is important, if you were to rely on that information in terms of approaching the HSNO legislation, I would urge you to have independent verification of the practices in relation to AVMAC because this is the point and Justice McGrath I think asked about it. Under section 14, certainly there isn't a register but under section 14 of that legislation which you don't have before you because it's not in that little bundle, the Director-General publishes a notice in the Gazette of an application.

My instructions from the people who have approached me today, the in house counsellor and the like, are that those Gazette notices always include the active ingredient because without it you can't engage with the application. It is true what my learned friend Ms Aikman says, that under the HSNO Act they can't actually approve, sign off the application until the HSNO application is determined but they will have already advertised the fact that the application, the active is there. So whereas when we all wrote our submissions we were

all, I think, working under the assumption that there was a temporal process here, that it went to HSNO, it finished HSNO, then it went to the Food Safety Authority, then finally it would come to marketing and temporal, my learned friends thought there would be a long period of confidentiality before the material was released on the product, at which time there would be the asymmetry between what was on the label and what was on the register. In fact, applications can be made first and are made first to the Food Safety Authority and they will advertise those I am instructed and only one in a thousand would be an innovative new compound and even that has the active advertised.

So, that's why my learned friend Mr Goddard was correct when he, just at the end, he qualified Ms Aikman's submissions about whether something would be available, it won't be available under the HSNO registration but it will be known under the advertising of the application in the Food Safety Standards Authority, the other piece of legislation. All that means, you may so what, well all that means is that the confidentiality window may be exceedingly short.

ANDERSON J:

Well it depends on when the applicant applies.

MR BROWN QC:

Yes, it does.

ANDERSON J:

I mean, if there was a low level of confidentiality the applications might be simultaneous. If there was a high level, they'll be staggered.

MR BROWN QC:

Well, that may be but his all came in through the submissions of the Amicus, these people came, they're not represented, we're all armed with this and I'm just concerned that you be aware that there is, in something that is no product of my submission, that there is the difference in it and this sort of temporality point which I rely on because I say that it's perverse to have, how ever long or

short it is, it's perverse to have a product out there with labelling that is a departure from the register, unless you say the register is really of no real consequence, that's the point in my court.

ANDERSON J:

It could be dealt with administratively though, couldn't it, with ERMA saying yes, we approve and one of the conditions of approval is that you notify us before product launch of what your product name is so we can update the register?

MR BROWN QC:

I don't accept Your Honour that there's any power to amend the register and indeed, it would be surprising if you then had a second unique identifier. That seems to be an inherent contradiction.

ANDERSON J:

Might have to prepare and maintain it, maintenance might mean adjustments.

MR BROWN QC:

Well, it's, you're introducing an interesting –

ANDERSON J:

It would save a lot of trouble if it's worked out what name they're going to launch under before they applied under this legislation.

MR BROWN QC:

Yes but Your Honour what brings us here today is the point that there would never be any need for them to do it because the Court of Appeal has ruled and it's the point I come to you with, that what is already there, (a), (b), (c), Mickey Mouse, Coca Cola and Your Honour meant Coca Cola when it wasn't but my learned friends I think thought you were describing actual drink but that is a sufficient description of the product and Coca Cola most clearly is not a sufficient description of anything other than Coca Cola. Anyway, that's really

all – I can't engage in the more elaborate than my learned friend's knowledge of wine, I would never seek to –

BLANCHARD J:

It's only a description of Coca Cola, if Coca Cola has been invented a long time ago and we all know.

MR BROWN QC:

I have strong views about the brevity of reply. Unless there's anything that you wish me to traverse, I will –

ELIAS CJ:

No, thank you. Thank you counsel for your submissions. It's been a long day and a very interesting day. Thank you. We'll reserve.

COURT ADJOURNS: 3.50 PM