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## INQUIRY INTO COMPULSORY LICENSING OF PATENTS

MS A. McCLELLAND, Presiding Commissioner DR W. MUNDY, Commissioner

### TRANSCRIPT OF PROCEEDINGS

AT MELBOURNE ON WEDNESDAY, 20 FEBRUARY 2013, AT 9.28 AM

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# **INDEX**

Page

PUBLIC HEALTH ASSOCIATION OF AUSTRALIA:

DEBORAH GLEESON

MEDICINES AUSTRALIA:

DEBORAH MONK

11-20

MATHEW RIMMER

21-33

**MS McCLELLAND:** Good morning, welcome to the public hearings for the Productivity Commission inquiry into compulsory licensing provisions in the Patents Act 1990. My name is Alison McClelland and I'm the presiding commissioner of this inquiry. My fellow commissioner is Warren Mundy.

We released a draft report on 14 December 2012 and have received a number of submissions on the draft report. The purpose of these hearings is to provide an opportunity for interested parties to discuss their submissions and their views on the public record. After considering all the evidence presented at this hearing and submissions, as well as other relevant information, a final report will be forwarded to government in March 2013. Participants in the inquiry will automatically receive a copy of the final report once released by government. Participants are not required to take an oath but are required under the Productivity Commission Act to be truthful in their remarks. Participants are welcome to comment on the issues raised in other submissions or by other speakers here today.

We like to conduct all hearings in a reasonably informal manner but I remind participants that a full transcript is being taken and will be made public on the commission's web site. For this reason, comment from the floor cannot be taken but at the end of proceedings for the day I will provide an opportunity for everyone wishing to do so to make a brief presentation. To comply with requirements in the Commonwealth occupational health and safety legislation you are advised that in the unlikely event of an emergency requiring evacuation of this building you should follow the green exit signs near the door and head to the left. Lifts should not be used in an emergency. Please follow the instructions of floor wardens at all times. If you believe that you would be unable to walk down the stairs, please advise the wardens who will make alternative arrangements. The assembly point for the commission in Melbourne is at Enterprise Park at the end of Williams Street near the bank of the Yarra River.

We would now like to welcome to the table Deborah Gleeson from the Public Health Association of Australia. If you could please for the record state your name and the organisation you are representing, and then if you would like to make some brief opening remarks or statement we'd be happy to hear from you, Deborah.

**DR GLEESON (PHAA):** Thank you very much, and thanks for the opportunity to speak to you today. My name is Dr Deborah Gleeson and I'm here representing the Public Health Association of Australia. I convene the Public Health Association of Australia's political economy of health special interest group and I act as a spokesperson for PHAA on public health issues related to trade agreements. I'm not an expert on intellectual property law and pharmaceuticals, I'm a public health policy generalist and I'll confine my comments to matters related to international trade agreements and public health.

PHAA is a national organisation of around 1900 public health professionals and it represents around 40 professional groups who have concerns related to population health. We're interested in the Productivity Commission's inquiry because we believe it's important to preserve and strengthen Australia's ability to use compulsory licensing to ensure equitable access to affordable medicines and other health technology.

We're also concerned about the effect that trade agreements can have on limiting the ability of governments to use strategies like compulsory licensing to achieve public health goals. Our policy position on trade agreements and health, which is available on our web site, states that policy space should be preserved in trade agreements for national governments to protect public health. So I'd like to speak to the submission made by PHAA to the Productivity Commission's inquiry, and we've also made a related submission to the Australian government's pharmaceutical patents review which we made with four other Australian NGOs, and that's publicly available on the review web site.

Our submission and my comments today are particularly relevant to one of the Productivity Commission's terms of reference for this inquiry that requires the commission to recommend any measures to efficiently and effectively exercise safeguards, such as compulsory licensing. While compulsory licensing hasn't been used for pharmaceuticals in Australia until now, it may well be necessary in future due to new epidemics and new diseases, shrinking health budgets or increases in the cost of pharmaceuticals and other health technology and things like drug shortages.

It's very important that we preserve domestic policy space to deal with these sorts of issues that may come up in the future. There has been a recent decision of Australia's Federal Court to uphold the patentability of isolated DNA and RNA sequences and to dismiss the challenge to Myriad Genetics' patent for the gene responsible for breast and ovarian cancer. So compulsory licensing is a critical safeguard that should be able to be exercised in the interests of public health consistent with the Doha declaration on the TRIPS agreement and public health which affirmed that the TRIPS agreement should not prevent members from taking measures to protect public health. That affirmed that each member have the right to grant compulsory licences and the freedom to determine the grounds on which such licences are granted.

The Productivity Commission issues paper, the first background paper, commented on the constraints that international treaty obligations can place on the efficient and effective use of compulsory licensing. However, there seems to have been little consideration given in the draft report to whether these treaty obligations are appropriate or necessary, and no attention given to a trade agreement that

Australia is currently involved in negotiating, the Trans-Pacific Partnership Agreement which may place further restrictions on the effective use of compulsory licensing for pharmaceuticals.

The Australia-US Free Trade Agreement introduced some restrictions on compulsory licensing which are noted in some of the Commission's papers, for example, limiting its use to cases of public non-commercial use, national emergency or other circumstances of extreme urgency. The Australia-US Free Trade Agreement also included a provision for five years of data protection for pharmaceutical test data for new pharmaceutical products which reinforce existing arrangements in Australia and reduce our domestic flexibility to modify or remove those provisions in future.

Data protection regimes effectively create monopoly rights that are distinct from and effective, even where a pharmaceutical product is no longer protected by a patent or when a compulsory licence has been issued. During the period of data protection, data that supports safety and efficacy that's been submitted to the Therapeutic Goods Administration can't be relied on by a generic manufacturer to obtain marketing approval for its product. Data protection constitutes an impediment to the effective use of compulsory licensing because the patent holder can prevent the marketing of generic equivalence by enforcing protection of test data, even when a compulsory licensing has been granted. As far as I'm aware this has not yet been tested in the courts but there have been cases where in the US and the EU where compulsory licences were rejected because of data exclusivity periods which were seen as barriers to those compulsory licences being effective.

I'd like to bring it to the Productivity Commission's attention that Australia is currently involved in negotiations for the Trans-Pacific Partnership which involves 11 countries, including the US, and leaked negotiating texts show that the US is pursuing extremely strong intellectual property provisions for this agreement that will reduce access to medicines. These US proposals have drawn heavy criticism from public health organisations around the world. In the Trans-Pacific Partnership Agreement, the US is seeking to extend both the duration and the scope of data protection, including at least five years' data protection for new pharmaceuticals, an additional three years for new uses of existing products and also to extend data protection to cover not just undisclosed data but data that's already in the public domain.

The US pharmaceutical industry is also pushing for longer periods of data exclusivity, possibly up to 12 years, to be applied to therapeutic biologics, which would include genetic materials. While the Australian government's negotiating position on the Trans-Pacific Partnership is that we don't want to change our domestic intellectual property laws and that Australia doesn't want to accept any provisions that would impede access to generic medicines in Australia, intellectual

property has become a sticking point in the negotiations, and it's possible that decisions about intellectual property may be made at the political level close to the end of the negotiations where trade-offs between different sectors may be made.

I'd also like to note that Productivity Commission's review of bilateral and regional free trade agreements in 2010 concluded that Australia should be very careful of any intellectual property commitments in future trade agreements. The Productivity Commission review report also noted that the Commission was not convinced that the approach adopted by Australia in relation to intellectual property in trade agreements has always been in the best interests of either Australia or most of its trading partners.

In this context it's vitally important that the Productivity Commission's inquiry into compulsory licensing conducts a thorough review of the current data protection provisions in Australia's trade agreements and their effect on compulsory licensing and recommends that provisions that would limit the effective use of compulsory licensing in future, including the US proposals for the TPP, are not accepted in Australia as current and future trade agreements. Thank you.

MS McCLELLAND: Thank you very much. Can I just ask you, in relation to the treaty issue we did have a recommendation in our draft report that we should remove the clause in the Patents Act that requires consistency with international treaties and that if there is any consistency that had to be put into the act. In other words, we're wanting greater transparency and clarity in relation to the effect of treaties on the Patents Act. Had you looked at that draft recommendation and did you have a view, given your concerns, about the impact of treaties on the Patents Act, the value of that recommendation?

**DR GLESON (PHAA):** I have noticed that recommendation and I haven't had time to fully consider what the implication of that would be. I'm happy to see that the Commission is considering the impact of international treaty obligations.

MS McCLELLAND: Given the terms of reference of our inquiry we would not be in a position to intervene in negotiations about where treaties are under way. The approach we're taking relates to transparency of the impact of treaties. So we would be interested in your views on that recommendation, that would help, but we'd need to have them quickly because we're finalising the report. It's going to be finalised over the next few weeks really.

**DR GLEESON (PHAA):** In what time frame would you need that?

**MS McCLELLAND:** We'll be putting the final report to the government at the end of March so within two weeks we will be finalising the report.

Patents 6 D. GLEESON pa200213

**DR GLEESON (PHAA):** If I'm able to I'll provide some comments on that. Thank you.

MS McCLELLAND: Yes, thank you.

**DR MUNDY:** Dr Gleeson, the government is recently introducing or may have even passed legislation with respect to compulsory licensing for exports to developing countries. I guess to the extent that your concerns relate to developing countries we're in a place now where we really need to see how that legislation goes. I understand that that legislation has led to one compulsory licence being issued in Canada in a similar fashion. That leads us to the question of access to pharmaceuticals and related biomedical products in a domestic context where our domestic law applies.

DR GLEESON (PHAA): Yes.

**DR MUNDY:** You spoke a lot about compulsory licensing but you said nothing about Crown use. Now, I would have thought that in a public health context that the most likely party to seek use would be the Crown rather than pursue some sort of compulsory licensing process because it's slower, there's more intervention by the courts and so on. Have you given any thought to whether, rather than compulsory licences being a method by which to deal with public health issues, it could be done under a Crown use provision which isn't subject to the constraints of section 136 of the Patents Act with respect to international obligations?

There seems to be no restriction on the Crown in the way there is upon the court in relation to treaties. We happen to think that the notion that the courts are bound by a treaty that came in - but in respect to that it's a bit odd. Have you given thought to whether the Crown use solves the public health issue, not only more effectively but gets around these other concerns?

**DR GLEESON (PHAA):** I haven't looked at that specifically but again I'm happy to consult with colleagues and come back with some comments.

**DR MUNDY:** Because what you'll find is that we are actually trying to improve the language of Crown use to make it pretty apparent that public health goes through without breaking the taboo of "there will be no technologic specific provisions in the Patents Act", to make it abundantly clear that public health is something where the Crown can use its rights to deal in intellectual property.

**MS McCLELLAND:** We have a draft recommendation that you might what to look at closely.

Patents 7 D. GLEESON pa200213

**DR GLEESON (PHAA):** Right. I'll get back to that. Thank you.

**MS McCLELLAND:** Warren's point about Crown use is I think the most relevant one. I suppose you did mention cases where compulsory licensing had been - I mean, if you've got any specific thing it would be useful to have them.

**DR GLEESON (PHAA):** I can send some information.

**MS McCLELLAND:** If you could let us have them very soon that would be helpful to us. I'm presuming that you've also provided your views to the pharmaceutical review.

**DR GLEESON (PHAA):** Yes, we have, thank you.

**DR MUNDY:** I have not thought long and hard about the issues of data protection and obviously the Crown use provisions, but why do you think it's an important issue for the compulsory licensing provisions of the act as opposed to the patentability standards and the parts of the act that go to when patent rights are protected? Surely it would be a better route to deal with the primary cause rather than to have some sort of backdoor way of dealing with the data protection issue through a compulsory licence, because compulsory licences are profoundly rare, whereas the issue that you're trying to deal with presumably is more general than in the context of compulsory licensing which is because patent holders refuse to grant access to the patent. That seems to be a method by which it doesn't cover the field of the problem that you're actually trying to address.

**DR GLEESON (PHAA):** Well, the problems associated with data protection are not just the fact that it may prevent the effective use of compulsory licensing, it also delays the entry of generic medicines, even in circumstances where a patent may have expired.

**DR MUNDY:** So could it be the case that the issues around data protection might actually be better dealt with somewhere else, particularly if we can carve out the treaty issue which then means effectively that the only thing that's relevant is what's legislated by the Australian parliament and then the data protection issues could be dealt with elsewhere as a more general concept?

**DR GLEESON (PHAA):** Well, we've made submissions to both processes because we would like to see recommendations being made that the Australian government shouldn't accept any stronger intellectual property protections. We think the system is already unbalanced. I mean, what compulsory licensing is about with respect to medicines is ensuring access in circumstances where there's a conflict between the

expectations of patent holders and public health, and we would want to see any inquiry into these sorts of issues recommending that no stronger intellectual property provisions are accepted in trade agreements that might constrain domestic flexibility around these issues.

**DR MUNDY:** I suspect when the compulsory licensing provisions of the act were written, public health wasn't what was in mind, that it was access to manufacturing goods like staple guns and things like that, but I take your point. I mean, I think the question of public health has arisen more recently and I think where we're trying to get at is if public health is what you're after, assuming that it's the Crown that deals with public health, rather than individuals, then perhaps Crown use is the place to deal with those issues, and making sure that the Crown use provisions are structured in such a way that they can be used for public health reasons, but also I guess the other issue we've been concerned with around this space has been making sure that the peculiarities of our institutional arrangements about funding and delivery in the health system don't trip us up if we want to use the Crown use provisions for public health reasons, just because of the funding issues and the public-private mixture of delivery models.

It would be helpful, I think, to us if you could have a look at Crown use and what we've said about Crown use and what we're trying to do with it, to see whether it addresses the public health concerns that you've got, both generally but also with respect to data protection because the issues of treaty, consistency with treaty doesn't arise in the current law and if our recommendations, of course, wouldn't arise in relation to compulsory licences either if we have our way.

### DR GLEESON (PHAA): Right.

**DR MUNDY:** But it would be useful to know whether the Crown use provisions in the mind of your organisation actually get where you'd like to be in cognisance of the fact that it's likely to be governments that are going to want to introduce the patents for public health rather than some private sector entity for whom the test should be higher.

#### DR GLEESON (PHAA): Thank you.

**MS McCLELLAND:** Yes. It seems to me that what Warren is also saying is that first of all the public health issues are probably best dealt with under the Crown use. Insofar as there are broad issues around data exclusivity, they relate to the operation of the patentee, the patent criteria and the length of patent which is a broader question than compulsory licensing and they're best dealt with in that. The way that treaties are conducted probably should be taken up with DFAT directly. We know there's other issues there - - -

**DR MUNDY:** I guess the other thing is, it's not possible for us to comment on a treaty that hasn't been signed and also the fact that it probably hasn't been subject to consideration by the Joint Standing Committee on Treaties of parliament.

MS McCLELLAND: Just being aware of what we can do under our terms of reference, in terms of responding to your concerns, I guess, I think they're the main points. It is worth having another look at our recommendation around treaties and our recommendations around Crown use too, and perhaps sending us any comments about that fairly quickly and any material that you do have about the relationship between data exclusivity and compulsory licensing.

**DR GLEESON (PHAA):** Okay. Thank you very much.

MS McCLELLAND: Thank you for your time. I think we're expecting the next person not until 10.15. They may be earlier, so in these circumstances we'll adjourn until they arrive. We might take a break until 10 o'clock and see where we're at in terms of whether the next person, Ms Deborah Monk, has arrived. We'll break for five minutes and you're welcome to have tea or coffee out there.

**MS McCLELLAND:** We will now recommence and would like to welcome to the table Ms Deborah Monk from Medicines Australia. If you could please for the record state your name and the organisation you are representing, then if you'd like to make some brief opening remarks we'd be pleased to hear from you.

**MS MONK (MA):** Thank you. My name is Deborah Monk. I'm the director innovation and industry policy at Medicines Australia. Medicines Australia is the peak body representing the innovative prescription medicines suppliers in Australia.

We would just like to commend the Productivity Commission on the draft report. When we understood that there was to be a review of the compulsory licensing arrangements in Australia that caused us some concern, because compulsory licensing is of concern to our industry on a global basis; not particularly in Australia but on a global basis it is of concern. So we would be concerned if there was any weakening of Australia's intellectual property regime that made it easier to obtain a compulsory licence for a pharmaceutical product in Australia.

We, for the most part, support the draft recommendations that the commission has proposed in its draft report. We have a couple of queries or questions about a couple of those recommendations but on the whole we support the draft recommendations that you are putting forward.

**MS McCLELLAND:** Thank you. Well, would you like to expand on the queries that you have?

MS MONK (MA): Yes, the two queries we had really was the proposal to amend or withdraw section 136 of the Patents Act which requires the operation of Australia's patent law with respect to compulsory licence to be consistent with Australia's international obligations. It was a little bit unclear to us whether you were proposing to do that and to incorporate into the legislation the text that would impose in Australia the requirements of our international treaties into the legislation, whether that was solely for the compulsory licensing elements of our international treaty obligations, or you were proposing for all of our obligations under international treaties to be incorporated into the Patents Act.

We felt that to do the latter to incorporate everything into the Patents Act where relevant would make it a very cumbersome piece of legislation, it may require frequent legislative changes as our treaty obligations evolve over time. It was a little bit confusing because in the summary of the recommendations it seems to refer to specifically just the compulsory licensing arrangements or whether it was all of our obligations under the international treaties.

**DR MUNDY:** You're aware that section 136 of the Act says that an order, and that means an order for a compulsory licence, shall - - -

**MS MONK (MA):** So it would be solely for that?

**DR MUNDY:** Yes. The recommendation specifically relates to section 136, and section 136, and I quote, "An order," and that's an order for a compulsory licence given by a judge of the Federal Court, "must not be made under section 133 or 134 that is inconsistent," with the Commonwealth's treat obligations. Now, that only relates to a compulsory licence order by the Federal Court.

MS MONK (MA): Okay.

**DR MUNDY:** So we've made no recommendations with respect to any other international obligation. But is it Medicines Australia's view that any treaty obligation entered into by the Commonwealth is binding on the courts?

MS MONK (MA): I'm not a lawyer, so - - -

**DR MUNDY:** Because there are a huge range of intellectual property obligations Australia up and enters into.

MS MONK (MA): Yes, indeed.

**DR MUNDY:** I would suggest to you that they're not binding until they're enacted by the parliament.

MS MONK (MA): You're probably correct, yes.

**DR MUNDY:** So I guess I'm interested in why this very isolated piece of intellectual property treat law should be treated any differently to our national obligations with respect to other areas of intellectual property - - -

**MS MONK (MA):** Yes, I see the argument.

**DR MUNDY:** --- perhaps under the Climate Change Convention, perhaps under the Biodiversity Convention, the Chicago Convention in relation to ---

**MS MONK (MA):** All of those are expected to be codified into our law.

DR MUNDY: Yes.

MS MONK (MA): Yes. I think it was because we were interpreting it in a much
Patents
D. MONK
pa200213

more broad scope than just with respect to the provision around compulsory licensing.

**DR MUNDY:** Well, I guess I'd invite you to read the recommendation again because that's certainly not its intent or the way it reads.

MS MONK (MA): Yes.

**DR MUNDY:** But I think it's a broader question you raise as to - well, I guess what I'd invite you to consider is that the patents law is enacted by the parliament in Canberra. If the executive goes and enters into a treaty obligation it has no force in Australia.

**MS MONK (MA):** Yes, and as you rightly say, when we have those treaties they need to be codified into the law in many cases.

**DR MUNDY:** All we're saying, I think, is that this should be the same as every other treat obligation of the Australian government.

MS MONK (MA): Okay, I can see that.

**DR MUNDY:** I guess the other observation I make, if I was a person seeking a compulsory licence - and let's say I'm not the government, I say I'm a small business seeking access and it mightn't necessarily be in medicines - would you think it would be easier for the person seeking the compulsory licence, or indeed for the person who the licence is being sought from, to deal with this legal question if they could simply turn to the statute law and see what the circumstance is; or would it be easier for them to have to trawl through the treaties database kept by DFAT to discover what obligations are actually relevant to the case in which they're being enjoined?

**MS MONK (MA):** No, I can see that. Yes, I agree. I think what we were reading is - I'm just trying to find the particular point in the report.

MS McCLELLAND: It's draft recommendation 6.3 on page 23.

**MS MONK (MA):** I think where we were looking to was on page 15 of the draft report where it says:

To remove any doubt, the clause in the Patents Act requiring consistency with international treaties should be removed. Current and future treaty obligations should be incorporated directly into the Patents Act or its subordinate legislation.

I think we were interpreting that in a much broader sense than you've explained, a much more specific sense.

**DR MUNDY:** Yes. Well, I think it's probably fair to say our view is that all treaty obligations should be legislated because otherwise they have no force, in domestic law at least.

**MS McCLELLAND:** So while the section to be repealed deals with compulsory licensing, the recommendation could apply to the Patents Act generally as it is read at the moment.

MS MONK (MA): Yes.

MS McCLELLAND: I don't think - you would agree?

**DR MUNDY:** Yes. No, but the general principle - the Commission's - and it is indeed the general principle promulgated by DFAT and the attorney's department is that treaty obligations need to be legislated specifically because they're not law if they're not, but also the language of treaties is very different to the sort of language that the courts are used to interpreting as drafted by parliamentary counsel and enacted by the parliament.

MS MONK (MA): Yes.

**DR MUNDY:** So it probably is better for people involved in these matters that it is in fact legislated in parliament so then it sits within the body of law, rather than some obscure language conjured up by diplomats which often isn't statutory language in its nature.

MS MONK (MA): I guess we're seeing an environment too where Australia is entering into a range of treaties. We've got the Trans-Pacific Partnership arrangement that will evolve over time and there could be changes to our current treaties. Just we felt that is that going to lead to progressive changes and lots of continual changes to the patents legislation as a result, if it's in the law?

**DR MUNDY:** Well, it's not the law if it's not in the law.

**MS MONK (MA):** Yes, I can see your argument.

**MS McCLELLAND:** One would hope that the negotiation of treaties has got regard to the legislation. So, you know, one would hope that they would have that effect as well, being careful in the negotiation of treaties in relation to what it does to our legislation. We were picking up from a number of submissions uncertainty about

the application - compulsory licensing arm because of the treaty. It wasn't clear, particularly after that treaty, what was allowed and what wasn't.

MS MONK (MA): Yes.

**MS McCLELLAND:** So it was our view that the legislation should be clear.

MS MONK (MA): Yes.

**DR MUNDY:** If it's legislated by the parliament then - - -

**MS McCLELLAND:** Yes, and it should have parliament - yes, it should be subject to parliamentary - - -

**MS MONK (MA):** As the normal course of legislative change we would have an opportunity to hopefully have an exposure draft to whatever that change would be.

**MS McCLELLAND:** Yes, exactly.

MS MONK (MA): Yes.

**DR MUNDY:** Which is the process that occurred around - there was legislation to give effect to the AUSFTA.

MS MONK (MA): Yes.

**DR MUNDY:** I think it's called the AUSFTA Implementation Bill or something like that - Act, something like that. So those normal parliamentary processes would apply.

MS MONK (MA): No, I accept that. The other point was a pretty minor point really, was in relation to the plain English guide. We recommended that the plain English guide should not just cover the Patents Act but should also cover the amendments you're proposing to the Competition and Consumer Act. It's a relatively minor point but the way the draft report was - text, it seemed to suggest it was solely around the Patents Act, but we would like to see everything, obviously, in one plain English guide.

**MS McCLELLAND:** Well, one would presume that any changes that are made by the government as a result of ours or other inquiries would be communicated well to the relevant people by IP Australia as required.

MS MONK (MA): Yes.

Patents D. MONK pa200213

MS McCLELLAND: We were particularly aware in relation to compulsory licensing that that was an area where there wasn't clear simple material on the web site. It was particularly that that we were referring to in relation to that recommendation. We did look at various options for this, by the way, about whether we needed to have a detailed - it was in our terms of reference asking us to look at this. We looked at various options as to whether we should have a detailed information campaign and so on. We concluded against that given that by and large - - -

MS MONK (MA): It's not often used.

**MS McCLELLAND:** The target is a very - quite a specialist target audience for this.

MS MONK (MA): Yes.

**DR MUNDY:** I think you make a fair point though, because the administration of the Competition and Consumer Act is in the hands of the ACCC. The administration of the Patents Act is in the hands of IP Australia.

MS MONK (MA): You wouldn't like to see the two bodies ---

**DR MUNDY:** Yes, I think a reasonable proposition. I mean, I think we could give some consideration as to whether IP Australia and ACCC should jointly develop a guide and it be available on both their web site so it has got a common - - -

MS MONK (MA): Yes.

**DR MUNDY:** I'm not historically a champion of the ACCC but they do have a bit of a knack of producing pretty good guides to various bits of the CCA. I think that's a fair point. To be frank, even if the government doesn't accept our recommendation to move the anti-competitive recommendations, IP Australia needs to work with the ACCC to deal with what constitutes breach anyway that would enliven the current provisions of the Patents Act. I think that's a point well made.

**MS MONK (MA):** They were the main issues that we wanted to mention, and I'm happy to respond to any questions that you might have of us in relation to our submission and our response to the draft report.

**MS McCLELLAND:** Just in relation to the Australian-US Free Trade Treaty, did you have a sense that there were any uncertainties about its application, because a number of the submissions did indicate that. Did Medicines Australia feel that it was

clear or unclear?

MS MONK (MA): I think the application of the Australia-US Free Trade Agreement often comes up when we are debating issues around IP, and we would say that certain things are consistent with the Free Trade Agreement and other parties might say that they're not consistent with the Free Trade Agreement. Just to give you an example there's a question about whether companies should be allowed to manufacture products that are protected by a patent in Australia for export to an overseas country. Now, we would say that that would be prohibited by the terms of the Free Trade Agreement and side letters, whereas other industry sectors might say, "Well, it's not prohibited by the Free Trade Agreement," so we have these debates about whether something actually is prohibited by the Free Trade Agreement or not.

Another issue that comes up is around data exclusivity or data protection arrangements under the Free Trade Agreement. Australia at the moment has compliance with the minimum level in the Free Trade Agreement. We would say that the Free Trade Agreement allows us to go beyond that which we would like to see changed, whereas other sectors might say, "Well, we only have to comply with the letter of the Free Trade Agreement."

Another debate we also have is about the implementation of what we refer to as the Latham amendments to the therapeutic goods legislation which is we interpret the Free Trade Agreement to require there to be a notification process to the owner of the originator product when a follow-on generic product is seeking application to register in Australia. The government has consistently said to us that the arrangements currently in effect through section 26 of the Therapeutic Goods Act - I think it's 26B, C and D - give full implementation to the terms of the Free Trade Agreement whereas we feel that those arrangements don't give implementation to what's required in the Free Trade Agreement. There is debate around how the Free Trade Agreement terms have been implemented and how they're interpreted.

**MS McCLELLAND:** Which might support our recommendation in terms of greater clarity.

MS MONK (MA): I think you might be right.

MS McCLELLAND: Yes.

MS MONK (MA): You may well be aware that your review of compulsory licensing is not only of interest to us in Australia but it certainly will have global implications. It's an area of extreme interest to our global industry. Although I don't have a lot of concerns with where you're going with the draft report, I didn't want to miss the opportunity of emphasising that point to you.

Patents D. MONK pa200213

**MS McCLELLAND:** Given that a lot of them are overseas patent holders, do you think there's any issues about subjecting someone from overseas to a compulsory licence application? Are there any issues there that you're aware of - - -

**MS MONK (MA):** Not that I'm aware of.

**MS McCLELLAND:** --- requiring them to appear before the Australian court when someone is wanting to take out a ---

**MS MONK (MA):** I think if there was a suggestion that a compulsory licence would be issued for a patent for pharmaceutical product in Australia, there would be lawyers from the global pharmaceutical company on the next plane. I don't think there would be any hesitation to be represented here in Australia.

**MS McCLELLAND:** The Crown use recommendation?

**MS MONK (MA):** We didn't have any particular concerns around that. It seemed to me that your recommendations were responding to the Department of Health's submissions about trying to make it clearer about how that operates.

MS McCLELLAND: Yes.

MS MONK (MA): We didn't have any concerns about that.

**DR MUNDY:** Do you think we succeeded?

**MS MONK (MA):** It sounds to me like it should make it much clearer, having read the Department of Health's submissions.

**DR MUNDY:** There's some issues in there about the legal meaning of words which the Parliamentary Counsel ultimately have to resolve, but we are trying to make it clearer for the benefit of all.

**MS McCLELLAND:** Primaries responsibility, for example.

MS MONK (MA): Yes.

**DR MUNDY:** I presume the other recommendations we make about Crown use on a legitimate attempt to negotiate and giving notice would be supported by - - -

**MS MONK (MA):** Yes, I think you also suggested that there needed to be some standards - is probably not the right word - about how you negotiate what's a fair

price to pay for that intellectual property.

**MS McCLELLAND:** Yes, we did.

**DR MUNDY:** We're trying to line up all the remuneration provisions so that considerations for remuneration under a compulsory licence are the same as they would be under Crown use - - -

MS MONK (MA): Yes, that makes sense.

**DR MUNDY:** --- because otherwise the prior negotiation framework doesn't work.

MS MONK (MA): One other thing that did strike me when I read the draft report, at one point you refer to the use of compulsory licensing in the United States, and I think you made a comment along the lines of that "it's frequently or commonly used in the United States".

**MS McCLELLAND:** Under different legislation. Yes, the power is used but it's under different legislation.

MS MONK (MA): Okay. Our colleagues in the pharmaceutical sector in the US thought that that wasn't the case in the US. So there certainly hasn't been a lot of compulsory licences issued.

**DR MUNDY:** The courts in the US and in Europe, because of the way their remedies provisions are structured in their antitrust law is what are effectively compulsory licences. They're not called that but they're used as remedies in antitrust cases. Their antitrust law operates differently to ours. But there's certainly been some in pharmaceuticals and there's been a lot in other forms of the economy.

**MS MONK (MA):** Could I suggest it might be helpful to explain that a little bit further in your final report just for clarity?

**MS McCLELLAND:** Okay. We'll have a look at the wording. Yes, because it is on the one hand or the other. They do use it a lot but it's not under that legislation or called compulsory licensing, so - - -

MS MONK (MA): Yes, okay.

**DR MUNDY:** They don't use it a lot but they're more common - more common than three or two.

MS McCLELLAND: Yes, that's a fair point.

MS MONK (MA): All right.

MS McCLELLAND: Okay. I think that's all I have.

**DR MUNDY:** Yes, thank you.

MS MONK (MA): Thank you very much for the opportunity.

**MS McCLELLAND:** Thank you for coming and for your submission. I presume we need to adjourn again for a short period while we establish contact with Dr Rimmer in Canberra who is going to appear via video.

MS MONK (MA): Thanks for your time today.

MS McCLELLAND: Thank you very much.

Patents 20 D. MONK

MS McCLELLAND: Thank you so much for coming and coming over so quickly and for your interest in our inquiry. So I'd like to welcome you. If you could please for the record state your name and any organisation you're representing and then if you want to make some opening remarks, we would be happy to hear from you. We've got 30 minutes for this conversation, Dr Rimmer.

**DR RIMMER:** Sure. My name is Dr Matthew Rimmer. I am an associate professor at the ANU College of Law. I am on the Australian Research Council future fellow, working on intellectual property and climate change and I'm also associate director of the Australian Centre for Intellectual Property in agriculture which has been going for a dozen years. So a wide variety of identities, though I'm appearing on my own behalf, particularly because I've had a longstanding interest in compulsory licensing, particularly in relation to access to essential medicines but also in other areas.

I guess I can do an opening and presentation too just in terms of an opening statement from me. The Productivity Commission has played a very valuable role in intellectual property policy over the years. In particular, I think the Productivity Commission has played a valuable role in some of the discussions about patent term, particularly in relation to the TRIPS agreement but also in relation to free trade agreements and the role of intellectual property in free trade agreements. I think the Productivity Commission has been particularly helpful in those discussions over intellectual property policy by providing an independent vision in relation to that topic and also demanding empirical evidence with the arguments that are put in relation to intellectual property matters. So I see it as a very positive development that the Productivity Commission is looking into the area of patent law and compulsory licensing.

Contextually, there's been I guess a range of policy problems in relation to patent law and compulsory licensing over the last decade or so. John McHugh and Henry Ergas valiantly tried to reform the compulsory licensing regime with their (indistinct) intellectual property and competition policy. To some extent they were frustrated in their efforts to try to reform that regime. There's been a lot of debate about compulsory licensing (indistinct) in relation to access to essential medicines, I guess there's been a great deal of controversy in Australia because in 2003, the WTO General Council Decision was established, setting up an export mechanism for the export of essential medicines to other jurisdictions to deal with (indistinct) concerns. 10 years later Australia is still working on its draft for the regime in relation to compulsory licensing to deal with essential medicines. I guess that is somewhat problematic, especially having a look at what's happened elsewhere, like in Canada with the Jean Chretien Pledge to Africa Act.

I guess in addition to that, there's been wider debates about patent law and compulsory licensing; in particular technological fields but also in relation to new free trade agreements, so the Australia-United States Free Trade Agreement and also in the current discussions in relation to the Trans-Pacific Partnership. So I guess that's kind of a context in terms of the very messy policy debate over the last decade in relation to patent law and compulsory licensing.

Sadly, I don't think that policy debate has necessarily fixed what has been a kind of broken regime in Australia, so I am hopeful that the Productivity Commission can improve upon past efforts and modernise the compulsory licensing system in Australia, both to take into account public interest concerns but also removing some of the ambiguity and complexity that's been apparent within the regime, but also I think engaging with some of the very difficult public policy questions that we've been hearing in this area.

So in terms of providing some feedback to your report, I guess I have three main themes or comments to make. I'd really like to discuss a little bit the discussion about the rationales for patent law and associated safeguards. I'd like to talk about some of the contexts in which battles over patent law and compulsory licensing have taken place. I guess my own company has cut across a number of particular contexts but I'm particularly interested in some of the issues in relation to agriculture and food security, clean technologies and climate change, gene patents and access to essential medicines.

Finally, I'd like to have a look at some of the key recommendations by the Productivity Commission. I guess just in a thumbnail way, I'm interested to hear exactly why you would want to move the competition testing ground from the patents regime into purely the competition regime. I guess in terms of your main recommendation in respect of reforming the compulsory licensing regime from taking the reasonable requirements doctrine and shifting to the notion of the public interest, I'd be positive in the sense that I think there are problems in terms of the way the current regime is articulated. I think it's kind of driven by an old domestic protectionist objective and I think the language is quite problematic.

I guess my submission today will be very much focused upon thinking about the ways in which you could define the public interest and I think there's an opportunity there to also think about factoring in to such discussions concepts about public interest relating to public health, the environment and education. So that's kind of an outline of some of the things that I'm interested in having a chat about with you.

I guess the first point in relation to patent rationales and rationales on intellectual property, I guess the key development that's kind of taken place since you Patents

22

M. RIMMER pa200213

released your report as being the High Court of Australia decision in JT International v Commonwealth and British American Tobacco v the Commonwealth. Plain packaging is one of my things. I was at the University of New South Wales last week talking about the genius of the plain packaging decision to 200 of Australia's public lawyers. I think that decision is very important, not only in terms of what it says about acquisition of property and the Constitution, but French CJ and some of the other judges of the High Court of Australia outline very systematically and clearly some of the objectives that are meant to be served by the various regimes of intellectual property. So the case involved not only trade marks but also patents, copyright designs and other purposes.

I think it would be useful for you in terms of thinking about your articulation of the rationales of the patent system to engage with some of the discussion in that case on that matter. French CJ emphasises in his judgment that:

There are and always have been purposive elements reflecting public policy considerations which inform the statutory creation of intellectual property rights.

He talks about the public policy dimensions of trade mark legislation, their interests in such dimensions accommodated in the Nike case. The judge emphasises that intellectual property laws create copyrights, are instrumental in character and negative rights.

The judges (indistinct) interesting though in terms of going through the different species of intellectual property, and thinking about the public policy considerations at stake, and in relation to patent law, French CJ emphasises that:

The Patents Act provides that a patent gives the patentee exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention.

### He notes that:

The origin of patents for inventions can be traced back to the Statute of Monopolies. That provision still forms part of the definition of "patentable invention" in the Patents Act. Its purpose was succinctly stated by Cornish, Llewellyn and Aplin. The terms of the section make it plain that an act of economic policy was intended (indistinct) industry employment and growth rather than just (indistinct)

I guess the draft report is also very interesting in terms of it takes into account questions about public health across all the different domains of intellectual property,

and I think it's a useful decision for you to contemplate when you're framing the objectives of the compulsory licensing regime and the patent regime.

The judge emphasises there's certain (indistinct) objectives served by patent law but they also have to think about the interactions with matters of public health and that kind of collision between the objectives of intellectual property regimes and other public policy matters often comes up in relation to debates over compulsory licensing. This particular case was corrected by the High Court of Australia to the views of the tobacco industry that they had private rights in relation to intellectual property lines that allowed them to broaden regulation or demand compensation. The High Court in this particular case said that intellectual property is governed by higher public purposes and that should (indistinct)

MS McCLELLAND: Could I just ask you a question about that, just because of the time we've got quite a bit to get through. So given that we do have compulsory licensing and we do have Crown use amongst two key things to enable that potential conflict between supporting property rights but also making sure that there's public access to the invention, I mean that's the basic reason why we've got Crown use and compulsory licensing. Apart from supporting the need to have those there as strong protections, what else would you do or what change would you make from that case?

**DR RIMMER:** Well, I think that indicates that you need to kind of take a broad conception of the public interest when thinking about matters of patent law and compulsory licensing. Sometimes the rationales in relation to patent law have been (indistinct) very narrowly, focused very much on private rights holders or limited public interest, like disclosure of information or some larger kind of economic (indistinct) I think the High Court of Australia decision is suggesting that one has to think harder about the interactions with the patent regime and other forms of public policy and I think the cases also can be interesting in terms of the High Court engaging a little bit with some large kind of questions about the objectives of intellectual property.

For my purposes the TRIPS Agreement is particularly important because that emphasises that members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors by audits to their socioeconomic and technological development and provide (indistinct) with the agreement and it goes on and talks about the need to take action to deal with the abuse of international property rights. I think at the moment there's a bit of a mismatch between the current objectives being served by the compulsory licensing regime and the flexibilities that are apparent under the TRIPS Agreement, particularly to deal with questions about public health and nutrition, the public interest in sectors of (indistinct) importance, matters of technology transfer. So I think the regime is not helpful in terms of

thinking about the purposes being served by the regime.

**DR MUNDY:** Just on the question of public health, surely given the Crown use provisions as they exist, and perhaps better constructed as we propose, in questions of public health, Commonwealth and state governments for that matter and under the current law local government, would be crazy to pursue a compulsory licence when they could simply enliven the Crown use provisions. I mean, the TRIPS Agreement is fine with respect to compulsory licensing but we have this other provision in our law which is not common across OECD jurisdiction whereby the Crown reserves to itself special rights to use patented materials.

Have you given any thought as to whether the Crown use provisions, as they are currently structured or as we propose, would actually get around those issues? I accept that the Crown use provisions are drafted in the terms of providing services rather than some other concept of public interest, but they certainly get closer to the mark then compulsory licensing provisions, I would have thought.

**DR RIMMER:** I think I would forcefully disagree with the suggestion that it would be crazy for a government to use compulsory licensing provisions in public health matters. I mean, I reckon in terms of domestic use like a country like Canada has used compulsory licensing to do with public health matters, and in the context of the international debates (indistinct) medicines, many countries have deployed compulsory licensing provisions for public health purposes, particularly Thailand and Indonesia - - -

MS McCLELLAND: Can we stop you for a minute there?

**DR MUNDY:** So if I was the Commonwealth Department of Health and I was wanting to, for a public health reason, gain access to a vaccine or something like that, it would be your view that the Commonwealth Department of Health would be better off to seek a compulsory licence, go through the Federal Court process and do all of that, or would it be better off to use the Crown use provisions?

**DR RIMMER:** I think the Crown use provisions have their own particular problems. I mean, this (indistinct) Australian Law Reform commission inquiry in relation to (indistinct) and the Australian Law Reform Commission itself was a little bit more enthusiastic about the Crown use (indistinct) provisions but personally I think as they're concurrently constructed they're very vague and ambiguous and have a lot of the problems that (indistinct)

**DR MUNDY:** So do you think our recommendations remove that vagueness?

**DR RIMMER:** I think the other point that I've made is that compulsory licensing is Patents
pa200213

M. RIMMER

available to a wide range of parties than just the government. I think there are issues sometimes trying to rely upon governments to take action by Crown use. I think historically, in relation to compulsory licensing, it's often been used for particular patent uses, like generic drug manufacturers, to have to seek action themselves in relation to (indistinct) a compulsory licence in relation to a measure. So personally I think at the moment (indistinct) on health grounds in terms of the way in which this is being addressed at the moment is that your recommendations in relation to compulsory licensing talk about the public interest which is all well and proper but is not necessarily very clear about what constitutes public interest in matters of compulsory licensing.

In relation to gene patents and essential medicines, I think you really need to kind of contemplate public health factors being taken into account in relation to matters of compulsory licensing, and I also say it seemed to me that in terms of your proposal I think you really need another compulsory licensing mechanism for humanitarian measures due to some of the public health concerns. At the moment your proposal for compulsory licensing is very much focused on there being able (indistinct) to deal with that particular invention. There needed to be some sort of approach to be made.

But in terms of the objectives being served by compulsory licensing in relation to the TRIPS Agreement, I don't see within your framework mechanisms to deal with national emergencies, circumstances of extreme urgency and public non-commercial use - - -

**DR MUNDY:** I'd perhaps invite you to read again the material on Crown use where we particularly go to questions of national emergency.

**MS McCLELLAND:** In which circumstances you would have the government acting so it's unclear how Crown use would not be the best thing to use in those circumstances.

**DR RIMMER:** Sometimes, sometimes not. I mean, in terms of some of their export mechanisms for compulsory licensing, sometimes you need a combination of different (indistinct) in those particular cases. So I guess my response would be I'm a little bit puzzled by your enthusiasm for Crown use, given the way the current rules have worked and given (indistinct) as they are. I think there are a wide range of circumstances dealing with matters of public health and climate change and food security where other (indistinct) will want to try and get access to (indistinct) other than a government entity.

**MS McCLELLAND:** Just to clarify, I think your major concern, Dr Rimmer, is that we haven't dealt sufficiently with the development countries' issues, rather than

the Australian domestic issues. Is that really what your key concern with our report is?

**DR RIMMER:** I mean, there's kind of a mixture of issues. To some extent the issues cut across one another in relation to access to essential medicines. There's the international issue in terms of access to essential medicines but there's also issues about what would happen, for instance, if there was a public health emergency in terms of something like the SARS virus, you know, raising a patent for the SARS virus. So I guess my comments in relation to the domestic regime is that you need to refine the notion of public interest. I think the public interest is a good starting point, but to my mind, it's not clear whether your notion of public interest is merely limited to quite economic matters or whether it will also take into account other possible factors in that context.

MS McCLELLAND: If you look at recommendation 6.2 and what we're saying about public interest, we very clearly say that it's related to Australian demand for a product service that's not been met on reasonable terms and access to the patent invention is essential for meeting this demand. That's a fairly strong, I would have thought, statement of public interest. So I'm just wondering why that isn't sufficient and why that's too economic.

**DR RIMMER:** Okay. Draft recommendation 6.2, I guess I'm really focusing upon 6.2 subsection (c), in which you talk about the costs to the patentee, benefits to consumers and the licensee from the licensee's access to the invention and longer-term impacts on community wellbeing. The larger public policy issues that are sometimes at stake in relation to battles of patent law and compulsory licensing sometimes raise larger questions. I guess I'm a little bit unsure from the language that you used in terms of "community wellbeing" whether you were to allow for, for instance, arguments about - to take, for instance, the gene patents controversy, and say the impact of the gene patents in relation to Myriad's patents (indistinct) clinical testing, administration, health care. Would they be useful factors to take into account in terms of community wellbeing or is it outside the kind of scope - - -

**DR MUNDY:** But with the greatest of respect, Dr Rimmer, the question in the Myriad case is the question fundamentally of whether a patent should be granted over isolated DNA or RNA segments and I don't think as a matter of legal policy the commission should be making recommendations with respect to compulsory licences that try and correct, whatever your view is - and the fundamental question in the Patents Act now is: what is patentable? So I don't think it's a remedy to that, irrespective of what your view on that matter is.

But you keep saying these "debates" and "conflicts" about compulsory licensing; to the best of our knowledge there have been three cases since Federation

Patents

27

M. RIMMER

relating to compulsory licensing. I guess I'm trying to understand what your view about this debate in a real policy framework actually is, other than around perhaps in gene patenting - a domestic debate other than around gene patenting - where some people probably erroneously thought that compulsory licensing was a backdoor way to do a patent definition. I'm trying to get at where is the real-world public policy problem that you seem to be enlivened by?

**DR RIMMER:** That's a very wide-ranging set of questions. To deal with the gene patents question, I mean (indistinct) the Myriad case that took place last week. Anyone who has looked at the battles over gene patents over the last decade would know that it's not just about patent subject matter, it's also been about novelty and inventive step and (indistinct) and there have been also questions about the efficacy of defences, like the defence of experimental use, and also matters about compulsory licensing. Now, I've looked internationally at the battles in the European Union, in Canada, in the United States and Australia, and that is a very real and apparent issue in terms of how compulsory licensing operates in circumstances in which there may be public policy demands.

I think the gene patents issue is a very kind of clear one in which government authorities and health departments around Australia have great difficulties in terms of contemplating whether or not they could bring some sort of action in relation to compulsory licensing to deal with that kind of particular problem. I think the commission in their approach to the topic hasn't really dealt with some of the problems surrounding it with (indistinct) I mean, President Barack Obama last week came out and said there was a deep abiding need to address patent reform in his second term, particularly dealing with the problem of so-called patent trials, non-practising entities which threaten litigation in respect of patent (indistinct) that has been a kind of international issue. But there's also been (indistinct) in Australia, so in the past (indistinct) over a US patent entity threatening the Australian government for patent infringement in relation to its electronic health records.

So I think in relation to the public health context, there has been quite a lot of debate about both research and development companies enforcing patents in a very aggressive fashion and also non-practising entities enforcing patents in an aggressive fashion. Prof Colleen Chien has done a very interesting study about how widespread that problem is across different disciplines in different sectors.

I guess your comment about, "Well, there's only been three instances where compulsory licensing has been raised," my response to that would be that the regime has been so awkward, so complex, so ambiguous, that a patent user would be unlikely to ever invoke those compulsory licensing provisions. So I don't think that the instance of those three occasions is necessarily an indication of the sorts of problems that are apparent at the moment. I think in terms of some of the other

**MS McCLELLAND:** Could I just say though, just in relation to your previous point about our public interest test, I think it would be useful for you to have a close look at that and point out how you don't think that will cover some of the situations you're concerned about because I actually think you possibly could, so we might be having a bit of a straw debate there, and whether your concerns could be covered by either our changed public interest test which is quite a broad test or the - - -

**DR RIMMER:** Sure, okay. Simply where I'm coming from, in my submission - I had a couple of submissions - one was on agriculture, the environment and climate change. I guess in relation to questions of the public interest, I particularly kind of emphasised that there was a need to pick up certain public policy objectives, particularly in terms of thinking about questions about public health, matters about the environment, climate change and food security. So I think there is a question about how you go about defining the public interest and what arguments you're going to allow parties to make if they're seeking a compulsory licensing.

I guess it's a bit unclear to me at the moment in terms of your current language about whether a party would be able to make those sorts of arguments. I was thinking particularly in terms of, you know, there's been lots of battles in relation to people and clean technologies. The best suit in the United States was between a company called Paice and Toyota - over the Toyota Prius in relation to hybrid cars. The case is kind of quite interesting, you know. Paice is a non-practising patent entity and they were successful in their action for patent infringement against Toyota.

When it came to remedies, the courts have required (indistinct) and took into account a range of different factors. Toyota, for instance, emphasised that hybrid cars are particularly important in terms of addressing concerns about the green economy and greenhouse gas emissions and they were able to make larger arguments about the public interest in the context of about whether or not there should be an injunction against them stopping production of the Prius altogether, or whether they should just have to pay some particular remedy.

So I think it is worthwhile having arguments about the public interest, in particular public policy areas. I guess some parts of the report currently engages some of those concerns, but in other parts of the report you seem less enthusiastic say in relation to climate change or food security, those kind of perceptions that you don't necessarily show much enthusiasm for some of the concerns that might arise in those areas.

**MS McCLELLAND:** I think the approach we've taken in those areas is we think a broad public interest test in compulsory licensing is the best way to deal with those

issues insofar as compulsory licensing is relevant to them, rather than having specific tests related to them. We have gone for the technologically neutral approach on the grounds that that's likely to be a better approach then specifying each technology which can lead to areas of omission.

**DR RIMMER:** I mean, I'm not necessarily arguing this particular point but you should have separate compulsory licensing regimes for different sectors. I'm merely saying you need to ensure that your regime is sufficiently flexible and adaptable to deal with different public policy concerns and interests. I guess I'm just a little bit concerned about - there are certain values there that are being (indistinct) chiefly in relation to questions about access and competition. I don't necessarily see a recognition about our particular concerns. I see some of the supplementary submissions raised similar concerns about, "Well, to what extent does this deal with public health considerations in terms of this test.

MS McCLELLAND: Okay. Thank you for that comment. I think we think we have but we'll just check that because I don't think there's any disagreement in the sense that the test needs to be a broad one that does protect the public interest in a range of areas. We're just running a bit short of time, we've only got five more minutes, so I think we need to deal with any critical issues that you haven't had a chance to comment on.

**DR RIMMER:** Okay. I guess my kind of main critique of the Productivity Commission report is I think that it really needs to set up a compulsory licensing regime to deal with access to humanitarian measures. I think in terms of the report there's a little bit on the Australian government (indistinct) billing on access to essential medicines. But I think that regime is a somewhat broad one in terms of it may be repeating some problems that have been experienced with some of the other regimes. Obviously it also doesn't take into account other scenarios in which access to humanitarian inventions may be pertinent and important.

I think it's very important that Productivity Commission take into account the need for an intellectual property regime to promote development, particularly in light of the long discussion paper, the WIPO development agenda that was promoted by John Barton and Francis Gurry at the World Intellectual Property Organisation. I think there needs to be more in the report on technology transfer. The International Centre for Trade and Sustainable Development has done some very good work on technology transfer, and I think that's an objective at the moment that's kind of missing in our current compulsory licensing regime.

I don't think provision of aid is necessarily a substitute for that, and I note a lot of the big aid organisations like MSF and Oxfam are very much of the view that one needs to reform intellectual properly to promote certain development goals. They

have very strong views about the need to modernise compulsory licensing regimes, particularly to do with those concerns.

I think in my submissions - I'd just like to kind of pick up some of the areas about food security, the environment and climate change. I'm part of a centre that deals with intellectual property and agriculture. We had a big conference last year on war and the future of food. Some of that work presented by some of the contributors at that conference might be of interest. Carlos Correa did a particularly interesting piece of work on intellectual property and food security and the need for flexibilities to deal with matters of food security. I think that kind of provides alternative views to ones that are put forward in the Productivity Commission report on that particular issue.

But there has been a lot of conflict in relation to patents and biotech. Yesterday the Supreme Court of the United States had the big case of Bowman v Monsanto which they just heard. They're the so-called seed wars. I mean we are a kind of independent research centre. We are conscious of the conflicts that take place between farmers and big biotech companies and some intermediaries. I think it's useful to think about compulsory licensing in relation to agriculture, especially because there's an accompanying regime in respect of the plant breeder's rights regime. So to answer your earlier question in relation to IP in agriculture, that's a very fraught issue, patents in relation to agriculture and biotech.

In relation to the environment I think it's worthwhile remembering that compulsory licensing has often been used to do with environmental matters, so the US Clean Air Act, for instance, has a kind of compulsory licensing regime. The Rio Plus 20 Future We Want text had a very interesting discussion about compulsory licensing but also other alternatives like public-private partnerships that were provided by Hillary Clinton and other mechanisms to try to provide access to patents that might affect environmental matters.

I guess in relation to intellectual property and climate change I think I would take issue with some of the other suggestions that were made to the Productivity Commission, particularly the one made by the Alliance for Clean Technology Innovation. That seemed to be - had a strange conglomeration of interests associated with it - and Exxon. Exxon is one of the big oil companies. It does have a few patents to biofuels but they're a kind of known as the big fossil fuels company. I think it's somewhat controversial for them to be trying to kind of portray themselves as a clean tech company and making recommendations about what is best for clean technology companies. General Electric is another member of that group. They have been involved in a lot of battles over patents and competition, particularly with Mitsubishi over wind turbines. Then there's also Vestas. I mean Vestas is a much more pure clean technology company that is focused upon renewable energy.

I've done a lot of work on the balance at an international level on IP and climate change. I think your report should probably be updated to catch the Doha discussions which just took place. So we had Copenhagen and then we also had Cancun and Durban and now Doha. Doha was quite interesting because there was a debate over intellectual property but it also led to the decision of setting up the Climate Technology Centre and Network which is going to be run by the United Nations environment program. In terms of - in your report you have other mechanisms to allow for access to patent technologies. That particular technology network I think is very worthwhile mentioning in that context as a kind of alternative mechanism to help share technologies.

But internationally, you know, there's such a division between those countries who want very strong IP rights protection in relation to (indistinct) technologies and those who want there to be flexibilities. I think it's perhaps worthwhile thinking a little bit about that particular issue. Last night at the ANU Climate Change Institute I heard Marlene Moses talk. She's the ambassador representing Nauru and the Alliance of Small Island States. I put there, you know, technology transfer question to her. I guess they're very kind of keen for there to be better processes for technology transfer whether by compulsory licensing or whether by other mechanisms like public sector licensing, open innovation or the Climate Technology Network.

**MS McCLELLAND:** Okay. So thank you so much. Now, I think we're going to have to sort of stop there. I just want to check that Dr Mundy doesn't have any more questions.

**DR MUNDY:** No, I don't.

**MS McCLELLAND:** So I think you've given us quite a lot of information. You presumably are available for us - to comment if we need to. We have your detailed submissions of course as well Dr Rimmer.

**DR RIMMER:** Yes. Look, I'm very happy to help the Productivity Commission in their efforts design a compulsory licensing regime that promotes the public interest. I mean I think that's very valuable. I'm not necessarily being kind of harsh in my criticism. I'm merely thinking about ways you could refine your domestic regime. So humanitarian issues is an important one. So there's just one thing I was interested before we finished.

MS McCLELLAND: Right.

**DR RIMMER:** I just read in here about your approach to competition and

Patents 32 M. RIMMER pa200213

compulsory licensing. I read your perspective about wanting to shift it across. I didn't quite fully understand - - -

**MS McCLELLAND:** Well, I'm going to have to be fairly quick about this because we've run out of time. But I'll say it quickly and Dr Mundy wants to add - - -

**DR MUNDY:** Given the time and we do have a phone call we have to make in three minutes, perhaps we could arrange for someone to give you a call and not for me to try and outline it in three seconds flat, because it's not trivial.

DR RIMMER: Sure.

**MS McCLELLAND:** So we'll arrange someone to give you a call about that and explain what we've done about - obviously we have tried to reduce uncertainty by having two - anyway, I won't - it is late. We have run out of time. We'll get someone to give you a call, Dr Rimmer, about that, to talk to you in some detail.

**DR RIMMER:** Okay. I'm hope you're talking to the ACCC about - - -

**MS McCLELLAND:** We have had extensive discussions with the ACCC and we've had support for our recommendations from the submission they have sent us. You can see that on our web site, Dr Rimmer.

**DR RIMMER:** Okay. Thank you very much.

**MS McCLELLAND:** So can I just say that, ladies and gentlemen, that concludes today's scheduled proceedings. For the record is there anyone else who wants to appear today before the commission? I adjourn these proceedings and that concludes the public hearings for this inquiry. Thanks for the dash, Dr Rimmer.

AT 11.27 AM THE INQUIRY WAS ADJOURNED ACCORDINGLY