POPIA does indeed apply to health research: A response to Bronstein and Nyachowe

To the Editor: Bronstein and Nyachowe[1] recently published an interesting and provocative article on data protection in health research in South Africa (SA). The main legislation that governs data protection in SA is the Protection of Personal Information Act 4 of 2013 (POPIA).[2] Contrary to the generally accepted wisdom that POPIA's conditions for processing of personal information apply to health research, the authors boldly propose that this is not the case. The authors' argument is based on section 3(2)(b) of POPIA, which reads: 'If any other legislation provides for conditions for the lawful processing of personal information that are more extensive than those set out in Chapter 3 [of POPIA], the extensive conditions prevail.' The authors suggest that the phrase *more extensive* in section 3(2)(b) does not mean more extensive protection of the rights of the data subject. Instead, the authors suggest that *more extensive* means 'more detailed, thorough or comprehensive'. Given that the corpus of extant health research legislation in SA is clearly more comprehensive than POPIA's own conditions in terms of its volume of rules, structures and procedures, the authors conclude that extant health research legislation in SA governs health research *to the exclusion* of POPIA's conditions for the lawful processing of personal information.

In this letter, I analyse the authors' argument and challenge two of its main aspects. My first challenge relates to the interpretation of the phrase *more extensive* in section 3(2)(b), and my second challenge to the rule level at which section 3(2)(b) operates.

The interpretation of *more extensive*

The authors highlight that POPIA serves an array of purposes. These do not only include protecting the right to privacy, but also the rights to access information and to the free flow of information. The authors suggest that the phrase *more extensive* in section 3(2)(b) does not mean more extensive protection of the rights of the data subject – with concomitant stricter obligations on health researchers processing such data subjects' personal information – but should instead be allocated its dictionary meaning of 'more detailed, thorough or comprehensive'. To show that SA health research legislation is more detailed, thorough and comprehensive than POPIA's conditions, the authors present in their supplementary document a comparative analysis of POPIA's conditions compared with corresponding provisions found in SA health research legislation and ethics guidelines. Strikingly, the analysis focuses on the sheer volume of legal and ethical rules, structures and procedures in health research legislation, with relatively little regard to the actual content of these rules. This is problematic from a constitutional rationality perspective, as the volume of rules, structures and procedures is an *arbitrary* measure that cannot serve to exclude POPIA's application. Accordingly, I suggest that the authors' interpretation of the phrase *more extensive* as 'more detailed, thorough or comprehensive' is not legally tenable. That said, what is the correct legal interpretation of the phrase *more extensive*?

Regarding the present state of SA law on interpretation, the Supreme Court of Appeal held that the 'inevitable point of departure is the language of the provision itself'.[3] Therefore, consider section 3(2)(b) again. It reads: 'If any other legislation provides for conditions for the lawful processing of personal information that are more extensive than those set out in Chapter 3 [of POPIA], the extensive conditions prevail.' The phrase *more extensive* relates to conditions for the lawful processing of personal information. Now consider the nature of POPIA's conditions for the lawful processing of personal information. These conditions are all – without exception – aimed at protecting the rights of the data subject. For example, accountability of the responsible party to the data subject; processing limitation to protect the privacy of the data subject; and purpose specification to protect the autonomy and dignity of the data subject. Accordingly, in the context in which it is used, the phrase *more extensive* relates to something – the conditions for the lawful processing of personal information – that by their very nature are aimed at protecting the rights of the data subject. It follows that a *more extensive* condition for the lawful processing of personal information would be a *condition that provides for the more extensive protection of the rights of the data subject*.

The consequence of this interpretation is that the volume of rules, structures and procedures is irrelevant. What matters is the *substance* of such rules – do they provide for more extensive protection of the rights of the data subject?

Before this question can be answered, however, one must determine the level at which section 3(2)(b) operates. Is it at the level of individual rules (i.e. conditions for the processing of personal information) found within other legislation, or is it at the level of the entire corpus of legislation pertaining to a field?

The rule level at which section 3(2)(b) operates

The authors state that 'POPIA does not apply in circumstances where more extensive *legislation* than chapter 3 of POPIA applies to the *field*' (emphasis added). As such, the authors suggest that 'The relevant question is whether the *sectoral legislation* is more extensive than chapter 3 of POPIA' (emphasis added). This is rhetorical sleight of hand, replacing *conditions* with either *legislation applying to a field*, or with its synonym, *sectoral legislation*. Section 3(2)(b) provides that where other legislation provides for *conditions* for the lawful processing of personal information that are more extensive than POPIA's own conditions, those extensive *conditions* prevail. Accordingly, the unit of comparison, which is also the unit that may prevail, is a *condition* in other legislation, not the other legislation as a whole. In practical terms, both the assessment of which legal rules are more extensive, and the consequent decision on which legal rules prevail, must be done at the level of individual *conditions* found in the other legislation.

The approach followed by the authors of positing an entire corpus of sectoral legislation as a unit of comparison with POPIA's chapter 3, and their conclusion that sectoral legislation in the field of health research excludes POPIA's chapter 3 in its entirety from applying to health research, is based on an incorrect interpretation of section 3(2)(b)'s level of operation – confusing *conditions* with *legislation*.

Importing the doctrine of pre-emption does not assist

The authors suggest that the doctrine of pre-emption can be useful. I do not agree. The doctrine of pre-emption is not part of SA law. In a previous article,[4] Bronstein herself stated: 'From what I have said it must already be clear that the doctrine of pre-emption cannot simply be adopted in South Africa.' In the same article, the author also stated that advocates of pre-emption would face 'profound conceptual difficulty' in the light of SA's Constitution. I agree with these past assessments by the author. Although SA law is, in principle, remarkably open to learning and borrowing from comparative legal

systems in appropriate cases, in the author's own past assessments the doctrine of pre-emption will face an uphill battle in this regard. Furthermore, it is simply the wrong battlefield. The doctrine of pre-emption applies to conflict between different levels of government (i.e. national v. provincial), and not to conflict between different statutes that operate at national level, such as POPIA and the National Health Act.

Furthermore, even if – for the sake of argument – the doctrine of pre-emption could be relied upon in the present context of POPIA's section 3(2)(b), it still does not take the author's argument any further, as pre-emption turns on legislative *intention*. Based on their mistaken interpretation of the phrase 'more extensive' and of the rule level at which section 3(2)(b) operates, the authors suggest that Parliament did *not intend* that POPIA should govern health research. However, when the mistaken premises fall away, so does the conclusion. Accordingly, the authors' reliance on the foreign doctrine of pre-emption obfuscates the issue, rather than clarifying it.

My thesis

The existing health research sectoral legislation in SA, considered as a whole, is indeed robust.[5] But while this robustness may be a relevant consideration in some POPIA contexts, such as applying to the Information Regulator for an exemption for health research projects from having to comply with certain of POPIA's conditions,[5] it is not a justification for the wholesale exclusion of POPIA's conditions from health research. When it comes to section 3(2)(b), the general robustness of health law sectoral legislation is not relevant. Instead, the focus must be on specific conditions for the lawful processing of personal information in such legislation. The correct question to ask is: Does a specific legal rule found in health research sectoral legislation provide more extensive protection of the rights of the data subject(s) than any of POPIA's conditions? If the answer is in the affirmative, such a legal rule found in health research sectoral legislation would prevail – but *only* that *specific* legal rule, and *not* health research sectoral legislation *generally*.

In the following paragraphs, I illustrate this principle by applying it to three examples.

Example 1: Minimality. Consider POPIA's minimality condition (section 10), which reads: 'Personal information may only be processed if, given the purpose for which it is processed, it is adequate, relevant and not excessive.' In their supplementary document, the authors note regarding the health research legislation equivalent of the minimality condition: 'Researchers are required to justify collection of data for a particular research project and the research protocol must be approved by the HREC [health research ethics committee].' No references to sections of legislation are provided, but I accept that it is correct. However, it refers to a procedural rule, and not to any substantive rule regarding minimality. One particular HREC may have its own guidelines on minimality, and another may not. According to the authors' own analysis with regard to the minimality condition, health research legislation evidently offers no corresponding substantive condition. Therefore, POPIA's minimality condition prevails in health research.

Example 2: Secondary research. POPIA (in section 15) does not require data subject consent for secondary research. However, the National Department of Health's 'Ethics in health research: Principles, processes and structures' (DoH Guidelines) require that if such secondary research is not within the scope of original broad consent, the research subjects should be re-consented.[6] In the case of secondary research, a condition for the lawful processing of personal information found in health research sectoral legislation is therefore more extensive than POPIA's conditions, and hence prevails.

Example 3: Data subject participation. POPIA's data subject participation condition entails that a data subject has the right (in section 24) to, *inter alia*, have his or her personal information that is held by a responsible party corrected. In their supplementary document, the authors state that there are detailed provisions for the correction of clinical records in the Health Professions Council of South Africa (HPCSA) Guidelines, Booklet 9.[7] The authors are correct, but the problem is that the HPCSA Guidelines, Booklet 9, only apply to *patient* records. In other words, they do not generally apply to all health research participants. Accordingly, POPIA's data subject participation condition fills a void in health research legislation.

Excursus: The issue of specific consent in health research

Bronstein and Nyachowe observe that I was involved in a debate on specific consent some years ago.[8-10] In this debate, Townsend and I[9] noted that it would be a misapplication of the legal doctrine of purposive interpretation to change the clear meaning of the word *specific*, as used in POPIA, to *broad*. What concerns me is that the authors mischaracterise our position in this debate. They suggest that we 'argue that the use of broad consent in health research is currently impermissible'. That is, however, not our position on broad consent. Our position is that broad consent *on its own is insufficient* for the purposes of compliance with POPIA. In our previous work, we provided examples of how health research projects can be planned using a combination of specific and broad consent in tandem, in order to comply with both POPIA and the DoH Guidelines at various stages of health research – including secondary research.[5,9,11] Accordingly, the notion that we argued that broad consent is somehow 'impermissible' is inaccurate.

Conclusion

The exploration of POPIA's section 3(2)(b) in the context of health research by Bronstein and Nyachowe is a courageous venture into legal *terra nova*. Although I suggest that the authors' argument is flawed, their article has initiated debate that will hopefully lead to more clarity on this important topic. I invite the authors to reconsider their position in the light of my arguments.

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D W Thaldar
School of Law, University of KwaZulu-Natal, Durban, South Africa
thaldard@ukzn.ac.za

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Building coherence in the regulation of health research: A reply to Thaldar

Bronstein and Nyachowe respond: Our article 'Streamlining regulatory processes for health researchers: To what extent does POPIA apply?'[1] examines the impact of section 3(2)(b) of the Protection of Personal Information Act 4 of 2013 (POPIA)[2] on health research. Prof. Thaldar provides a helpful response to our article in order to develop the debate about the application of POPIA to health research.

Section 3(2)(b) of POPIA reads as follows:

'(b) If any other legislation provides for conditions for the lawful processing of personal information that are more extensive than those set out in Chapter 3 [of POPIA], the extensive conditions prevail.'

Section 3(2)(b) sets out the circumstances in which other legislation prevails over the conditions found in chapter 3 of POPIA. In our article, we argue that the sectoral legislation that governs health research provides more extensive conditions for the lawful processing of personal information than chapter 3 of POPIA does. The sectoral legislation for health research therefore prevails over chapter 3 of POPIA.

Section 3(2)(b) of POPIA is an enigmatic provision that needs to be interpreted in a way that makes the law as coherent as possible. Prof. Thaldar disagrees with our suggestion that the sectoral legislation for health research prevails over chapter 3 of POPIA *in its entirety*. The disagreement between us takes a technical turn, so we will start by giving an explanation of the concepts that we use.

Our interpretation is that Prof. Thaldar favours a direct conflict test to manage conflict between POPIA and the sectoral legislation, while we advocate use of an interpretive device similar to field pre-emption. The direct conflict test asks whether two legislative provisions can be obeyed at the same time. If they can, then there is no conflict between them and both pieces of legislation should be obeyed simultaneously. If there is conflict between them, there needs to be a rule about which piece of legislation prevails. Prof. Thaldar proposes that the legislative *provision* that gives the most comprehensive protection to data subjects should prevail. The consequence of Prof. Thaldar's approach is that the legal interpreter bounces back and forth between POPIA and the sectoral legislation looking for the provisions that provide most protection to data subjects. The question of which legislative provision applies to a particular aspect would need to be decided on a case-by-case basis depending on which is most advantageous to the data subject. An important problem with this method is that a new regulatory scheme is fashioned through a haphazard process of comparison. A product is created that could never have been considered or intended by the legislature. In addition, the interests of data subjects are mechanically prioritised over the social interest in health research.

Our approach is different, because we argue that a device analogous to field pre-emption is encoded in section 3(2)(b) of POPIA. Field pre-emption is a legal concept that was developed by judges in the USA and Australia in the context of federalism jurisprudence. In outline, the doctrine of field pre-emption is as follows:

1. In the USA competent federal (national) law prevails over state (provincial) law.
2. Under the doctrine of field pre-emption, even if the national legislature has not explicitly said that state law is overridden by federal legislation, 'state laws cannot stand if they … interfere with a comprehensive regulatory system set up by Congress [i.e. the national legislature]'.[3]

The analogy is that section 3(2)(b) of POPIA tells us that other legislation prevails over chapter 3 of POPIA where that other legislation provides more extensive conditions for the processing of personal information than chapter 3 of POPIA does. To paraphrase: the provisions in chapter 3 of POPIA cannot stand if they interfere with a comprehensive regulatory system set up in sectoral legislation. We therefore argue that the sectoral legislation applies to the exclusion of chapter 3 of POPIA.

In the paragraphs that follow, we deal with Prof. Thaldar's response to our article in detail and elaborate on the conclusions presented in our article.

The disagreement

Prof. Thaldar disagrees with our interpretation of section 3(2)(b) of POPIA. He correctly characterises our argument about the applicability of POPIA to health research in the following way:

1. The conditions for the lawful processing of personal information, as provided in chapter 3 of POPIA, do not apply to health research in South Africa (SA). This is based on our interpretation of section 3(2)(b) and particularly our interpretation of the words '*more extensive than*' used in that subsection.
2. Consequently, the sectoral legislation regulating health research ought to apply to the exclusion of chapter 3 of POPIA. This is based on our analysis that the sectoral legislation is more detailed, thorough and comprehensive and hence 'more extensive than' the conditions set out in chapter 3 of POPIA.
3. Based on this, we argue that chapter 3 of POPIA does not apply to health research.

Prof. Thaldar argues that we use the wrong unit of comparison in our article. In his view, our mistake is that we compare the two legislative schemes (which are chapter 3 of POPIA on the one hand and the sectoral legislation that regulates health research on the other). In his opinion, section 3(2)(b) requires a comparison of individual legislative provisions. In other words, he argues that it is necessary to ask the following questions in order to establish which legislation prevails:

1. Does a specific legal rule found in the sectoral legislation for health research provide more extensive protection of the rights of the data subject(s) than any of POPIA's conditions?
2. 'If the answer is in the affirmative, the legal rule found in health research sectoral legislation would prevail – but *only* that *specific* legal rule, and *not* the health research legislation *generally*.'

We therefore suggest that Prof. Thaldar explicitly adopts a direct conflict test to establish which legislation prevails.[4]

Prof. Thaldar is correct in pointing out that when we analyse the meaning of section 3(2)(b), our unit of comparison is the corpus of legislation. We compare the sectoral legislation for health research with the conditions in chapter 3 of POPIA in order to determine which

is more extensive. Prof. Thaldar's analysis requires a comparison of particular provisions of POPIA with individual legislative provisions in the sectoral legislation. His argument faces an extra hurdle, as he has to establish a basis for comparing the provisions. In order to solve this problem, he argues that the legislative provision that best protects the data subject prevails over the one that does not.

Primacy of the rights of data subjects

Prof. Thaldar argues that the privacy interests of data subjects are paramount in POPIA. Section 3(2)(b) of POPIA therefore needs to be interpreted in order to maximise the protection of data subjects.

In our view, Prof. Thaldar's argument does not cohere with the multiple legislative purposes that are set out explicitly in section 2 of POPIA (also see section 3(3) of POPIA). We agree that POPIA has the important purpose of protecting the rights of data subjects – but at the same time, the Act regularly limits those rights in a way that is justifiable under the limitation clause of the Constitution. POPIA also engages with other constitutional rights, most notably the rights to freedom of expression and access to information. For example, section 7 of POPIA creates a journalistic exception that is necessary in a democratic society. It seems to us that the argument that section 3(2)(b) always needs to be interpreted in a way that gives maximum protection to data subjects cannot be sustained.

A preliminary point: Recourse to federalism literature and the doctrine of pre-emption

We argue that the doctrine of field pre-emption is a useful tool for interpreting section 3(2)(b) of POPIA. Prof. Thaldar criticises our recourse to the doctrine on the basis that it has never been part of SA law. Rather, it is part of US and Australian federalism jurisprudence. Prof. Thaldar points out that all the legislation mentioned in our article operates in the national as opposed to the provincial sphere. He also quotes one of us who had previously shown that the doctrine of pre-emption cannot simply be applied to federalism jurisprudence in SA.[4] So far, all Prof. Thaldar's observations are manifestly true.

So, what is our justification for raising foreign federalism jurisprudence in this context? Although section 3(2)(b) of POPIA is a very unusual provision, it is uncontroversial that it sets out circumstances in which the conditions in chapter 3 of POPIA will not prevail.

The federalism literature is useful because it demonstrates the complexity of resolving conflict between two corpuses of competent, valid legislation operating in the same field or appearing to regulate the same subject matter. The limitations of the direct conflict test for dealing with conflict between national and provincial legislation are well documented.[5] In response to these difficulties, judges in the USA and Australia have fashioned indirect conflict tests and developed the doctrine of field pre-emption. (If one wishes to avoid resorting to the doctrine of field pre-emption, it is possible to get the same results using what is known as an 'indirect conflict test' for legislative conflict.[6]) In any event, the doctrine of field pre-emption originates from case law that applies tenets of statutory interpretation that are shared by all common law jurisdictions. In our view, the doctrine of pre-emption has much to add to the current debate. We will show later that the pattern of reasoning in the pre-emption cases resonates with the type of legislative conflict invoked by section 3(2)(b) of POPIA.

Prof. Thaldar emphasises that all the legislation mentioned in our article is national legislation. In our view, this simplifies matters. Our circumstances are automatically less politicised than they would be if we were dealing with a federalism dispute. (For example, see the highly politicised US dispute about whether FDA regulation of abortion medications pre-empts state laws that ban abortion.[7]) In our case, we are not dealing with contestation about which political authority has power over the subject matter. Parliament has the power to amend POPIA or any of the sectoral legislation for health research in order to give full effect to its intention.

The unit of comparison: The specific provision or the corpus of legislation

We argue that the appropriate unit of comparison for the purposes of section 3(2)(b) of POPIA is the corpus of sectoral legislation regulating health research. We compare this body of legislation with the conditions in chapter 3 of POPIA as a whole. We argue that when the two legislative fields are compared, the 'more extensive' one prevails.

Prof. Thaldar's direct conflict test for dealing with legislative conflict conceptualises both POPIA and the sectoral legislation regulating health research as if they were compilations of discrete rules. This mischaracterises the legislative schemes, which are both infused with legal principles.

The doctrine of field pre-emption is designed to be respectful of the regulatory architecture of conflicting legislative schemes. It incorporates a 'spatial metaphor' for conceptualising legislative conflict.[6] In the federalism context, judges use the doctrine of pre-emption in circumstances where the national legislation 'establishes a complete and exhaustive regulatory scheme' that conflicts with state or provincial legislation.[6] The pervasiveness of competing legislation is an 'important benchmark' that encourages judges to take the view that a particular corpus of national legislation prevails over competing legislation.[8] Pre-emption operates in circumstances where the legislative field appears to be 'fully occupied' or where the prevailing legislation does not leave space for conflicting legislation.[9] In the federalism context, if the Court finds that the legislative field is fully occupied by national legislation, then the national legislative scheme prevails *in toto*. As a consequence, the individual provisions in the competing (provincial) legislation are submerged and do not apply.

We suggest that the doctrine of pre-emption is effectively baked into the wording of section 3(2)(b) of POPIA. As with pre-emption, the comprehensiveness of the competing legislative scheme or its *extensiveness* determines which legislation prevails. The doctrine of pre-emption provides an elegant solution to the interpretive difficulties posed by section 3(2)(b) of POPIA in the health research field.

More compellingly, our argument about the correct interpretation of section 3(2)(b) treads carefully on the SA corpus of sectoral legislation for health research. That is appropriate, because in our view, the provisions in the sectoral legislation reflect 'neither a maximum nor a minimum standard but one representing a unique balance of considerations'.[9] The sectoral legislation balances the interests of data subjects with the social interest in ethical medical research that is as safe as possible. In our view, section 3(2)(b) of POPIA has the impact of preserving and prioritising the corpus of sectoral legislation as a coherent whole to the exclusion of chapter 3 of POPIA. We therefore reject Prof. Thaldar's criticism that our analysis focuses on the 'sheer volume of legal and ethical rules, structures and procedures, with relatively little regard to the actual content of these rules'. Far from being an 'arbitrary measure', each of the 'rules, structures and procedures' reflects particular legislative choices made in the context of health research, and they should be implemented.

Our view is fortified by the presumption in the interpretation of statutes that 'when the legislature has given attention to a separate subject and made provision for it, the presumption is that a subsequent

general enactment is not intended to interfere with the special provision, unless it manifests that intention very clearly'.[10]

The specific examples raised by Prof. Thaldar

Minimality. Prof. Thaldar suggests that the sectoral legislation for health research offers no corresponding condition to the principle of minimality found in POPIA. He does, however, partly accept our statement that the minimality principle finds expression in the ethics approval process – in the sense that researchers are required to justify collection and use of data before their research protocols can be approved. Prof. Thaldar correctly points out that the latter requirement is procedural and not substantive, although scrutiny by a health research ethics committee (HREC) is a rigorous requirement. There are also instances where the substantive aspect of minimality is specifically encoded in the National Department of Health 'Ethics in health research: Principles, processes and structures' (DoH Guidelines).[11] For example, paragraphs 3.2.2.1 - 3.2.2.4 only allow children to participate in health research 'when their participation is scientifically indispensable', and then they can only be exposed to 'minimal risk'.[11]

Minimality is a core concept in the General Data Protection Regulation and POPIA because it protects the freedom and autonomy of data subjects. On the other hand, Wouters *et al*.[12] point out that '… the principle of data minimization seems to conflict with the usage of big data analytics in health and research'.

We agree with Prof. Thaldar's observation that minimality is not a high priority in the sectoral legislation regulating health research. In our view, this points to a strength and not a weakness in the sectoral legislation. HRECs need to approve data collection and use for health research. They are expert bodies that are best positioned to protect the interests of data subjects without stymieing the benefits of health research.

Secondary research. We agree with Prof. Thaldar that the sectoral legislation for health research prevails over POPIA.

Data subject participation. Prof. Thaldar refers to the fact that POPIA gives data subjects the right to have their personal information corrected. Although he acknowledges that patients have a right to have their health records corrected (and clinical data are often used in health research), he takes the view that the sectoral legislation does not extend the right of correction to all health research participants. He argues that POPIA 'fills a void in health research legislation' by providing a right of correction to all participants in health research.

We do not agree that there is any gap or void in the sectoral legislation for health research. The DoH Guidelines prioritise the need for accurate data. If any inaccuracy is pointed out by the data subject or anyone else, researchers have a duty to promptly correct the record. (Transparency and openness are fundamental principles in the DoH Guidelines – see paragraphs 6.3.11 of the Health Professions Council of South Africa Guidelines, Booklet 13,[13] and 3.5.2.3 of the DoH Guidelines.[11]) This fortifies our argument that the sectoral legislation occupies the entire health research field.

Conclusion

The contributions made in this debate evidence the importance of clarifying the application of POPIA to health research. We are grateful for the constructive engagement with Prof Thaldar. We do, however, stand by our position about health research generally as well as our position on consent in particular. Section 3(2)(b) of POPIA puts health researchers and institutions that conduct health research in a position where they have to decide whether to apply POPIA's conditions or other legislation. This debate has shown that this exercise ought to be carefully considered.

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V Bronstein, Advocate of the High Court of South Africa
Associate Professor, School of Law, University of the Witwatersrand, Johannesburg, South Africa
victoria.bronstein@wits.ac.za

D T Nyachowe, on behalf of the MADIVA Research Hub
Junior Researcher, Sydney Brenner Institute of Molecular Bioscience, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

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