Ambiguities in the making of an African Medicine: clinical trials of *Sutherlandia frutescens* (L.) R.Br \(^1\) (*Lessertia frutescens*).

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**Abstract**

This paper attends to the large and heterogenous array of people and things that come together in the making of a medicinal plant, *Sutherlandia frutescens* (*Lessertia frutescens*) as an African medicine through clinical trials. It is a messy, contested and ambiguous process and is constantly being revised and is always open to surprises and the possibility of failure. I use *Sutherlandia* to introduce some of the issues that complicate the landscapes of knowledge in South Africa in relation to phytomedicines and pharmaceuticals.

**Keywords:** *Sutherlandia frutescens*, trials, knowledge, plant, medicine

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\(^{1}\) The plant has been reclassified under the genus *Lessertia*, but, since it is widely known as *Sutherlandia frutescens* (*S.frutescens*), I will use this name throughout.

**Introduction**

In a small settlement on the West Coast, Mrs B, a professional woman has for the past two years been drinking a litre a day of the bitter plant infusion to combat her diagnosed cancer. Where she lives, the plant is called *kankerbos* (cancer bush). In an old age home in Worcester, an elderly man, Mr A, shows me dried plant stems and leaves which his grandson picked for him in the veld on his farm. Mr A applies mashed leaves as paste to cancer lesions on his skin. In Cape Town, a grandmother in Bonteheuwel, Mrs C, grows the plant in her garden and gives a deduction to a recently widowed woman to ‘build up her system’. In Knymsna, Mrs D regularly orders a kilogram of the dried chopped up plant from a farmer from the Western Cape coastal area. Mrs D puts two spoonfuls into a litre of boiling water, cools it in the fridge, and gives her diabetic husband a glassful every morning. A herbalist from Strand, Mr X, calls the plant *unwele* (hair) and sells it to local traditional healers (*isangoma*), or mixes up a brew with other plant medicines for clients. Mrs H, a traditional healer in Khayelitsha mixes this same plant with other plant material and prepares a bottle of the decoction for a woman who complains of listlessness, weight loss and diarrhoea. Mrs H strengthens the activity of the plant through drumming sessions and prayers to the ancestors.

The plant that all the above people use is the *Sutherlandia frutescens*, one of the plants used most widely in South Africa to treat a variety of illness conditions *Sutherlandia* is known under a variety of local names such as *kalkoenbos*, *blaasbossie*, *blaas-ertjie*, *cendjie*, *klapper*, *hoenderbelletjie* (*Afrikaans*), *insiswa* (*dispels darkness: Zulu*), *unwele* (*hair: Zulu*), *phetola* (to change: *Tswana*), *lerumo lamadi* (*spear of the blood: North Sotho*), *mkakama* (*Tswana*), etc. *Sutherlandia*, a versatile plant, is utilised by lay people, herbalists (*inyanga*), diviners (*isangoma*), bush doctors (*bosiedokters*), Rastafarians, practitioners of alternative medicine, as well as a number of allopathic clinicians (Gerickie, 2001; Pappe 1947, 1850; Roberts 1990; Smith 1966; van Wyk et al 2002).

*Sutherlandia* is grown commercially, in a number of community based medicinal gardens and sold to natural product producers, local users, herbalists, *amayeza* shops and *muhiri* markets. It has, for some time, been available on the South African market as plant material, ground up, sometimes mixed with other plant materials, as powdered plant tablets, as liquid plant extract and is taken to treat a range of ailments and symptoms associated with, inter alia HIV, cancer, infections, inflammation, stress, tuberculosis, diabetes, arthritis and peptic ulcer (Johnson et al 2007; Oloyede 2010). *Sutherlandia* has a long record of medicinal application in South Africa dating back to colonists at the Cape, who probably learned about its medicinal value from the San and Khoi (Pappe 1847;1850). It is one of the most popularly used and sold medicinal plants in the Western Cape (Mintza Mi Nzue 2009) and is widely presented as an indigenous medicine for the whole country. *Sutherlandia* capsules are available on the market and have been used with apparent positive clinical results for outpatients living with AIDS...
Sutherlandia is at the centre of much disputation. Traditional medicines are supposedly based on untested cultural beliefs, and as mainly consisting of a placebo or meaning effect (Geffen 2010, cf Richter 2003, Moerman and Jonas 2002). There are all kinds of politics and contestations about indigenous knowledge and science at play in relation to this plant and medicinal plants generally. For example, when a collaborative endeavour was first formulated for the testing of African traditional medicines as plant medicines, rather than as purely pharmacological components, it was negated by a number of scientists as ‘dancing in the entrance hall of the devil’, ‘a witches brew’ and as pseudoscience, rather than as a scientific endeavour to isolate active ingredients. A study of traditional medicine was seen as unscientific and predicated on ‘their (local population’s) beliefs about and experiences of herbal medicine’ and thus on ‘culture’, (IK), rather than rational evidence.

Such a study does not easily fit into models of trials for individual pharmaceutical components or molecules. In relation to herbs used in Tibetan Medicines, Adams highlights the problematic of the testing and making of ‘medical facts’ from ‘beliefs’, the economic and political imperatives surrounding randomised controlled trials and the ambiguous, or even negative, outcomes it may have for those who use the traditional medicines. The testing of a medicinal plant is not the same as testing a pharmacological component, but it is perceived as a contribution to the advancement of indigenous knowledge in a fusion with science.

This paper explores ways to think about science as material practice. I draw on Law (2007), Mol (2002), Stengers (2010) and Latour (2005) to show how knowledge emerges out of contestations about validity and where politics is also made out of a traditional medicine. A great deal is at stake: Sutherlandia is in a sense a litmus test for the emergence of a new, hybrid knowledge domain, a potential model for research on traditional medicines, the development of regulatory guidelines around such kinds of clinical trials and the registration of traditional medicines of, from and in South Africa. It is the first, and up till now the only, indigenous plant to be tested through randomized placebo controlled clinical trials in the country. This process, this making of both knowledge and plant medicine, is evolving all the time, but it is simultaneously being contested and very fragile.

In the making of an African medicine through clinical trials apparently unrelated and even conflicting knowledge practices, such as biochemistry, medicine, indigenous healing, self-medication, regulatory frameworks, politics and such come to develop a relationship which benefits them mutually. In a Latourian sense, I try to follow the trail of the trial (at least its beginnings) by trying to describe the making of a heterogeneous work-net of aligned interests and of its ordering effect in practice. I show that making a plant medicine involves the messy process of making complex connections between things and people through a process akin to the tying of a net, or what is called an actor-network that comes about. This paper is about practice and distinct from Oloyede’s (2011; in this volume) concern about mainstreaming and outcome. However, as Oloyede (ibid) suggests, it points to a not straightforward, but rather ambiguous process.

Sutherlandia has been tested for safe use, first in vervet monkeys, then in healthy humans in a randomized double-blind placebo controlled clinical trial. This was done at a trial site in Cape Town where 25 adults took 800mg of dried leaf powder (or a placebo) for three months. Oloyede (2010; this volume) describes this in detail. Currently Sutherlandia is also being tested for safety (Phase 1) and efficacy (Phase 2) in people with HIV with a CD4 count above 250 and who are not on antiretrovirals (Oloyede 2011). The study, which will soon come to an end, is being done in two sites in Kwazulu-Natal. The protocols for another trial in Cape Town, this time with capsules filled with freeze dried, powdered Sutherlandia has been submitted to the Medicine Control Council for clearance. This latter project is funded by the Department of Science and Technology.

**Making sense of Sutherlandia and its trials**

According to Law (1992) knowledge is actualized in a whole range of material forms and is the result of a great deal of work in which assorted things — compounds, assays, test tubes, reagents, molecules, standard operating procedures and skilled people, statisticians, biochemists, pharmacists, clinicians and other entities — that would abscond by themselves, are put together in a patterned network which, at least momentarily, surmounts their resistance. In the case of the trials, an African reversed pharmacology model was envisaged, composed and performed into being. For the purposes of a clinical trial, however, it needs to be enacted as one, a plant medicine based in indigenous knowledge and a single botanical entity, clinically tested and studied in laboratories and hospitals. Sutherlandia tags contesting ideas about knowledge, science and the appropriate models to ‘test’ an African traditional medicine.

In South Africa the uncertainty surrounding Sutherlandia is evidenced in newspaper banners and online sites that refer to the great Sutherlandia debate, or ask ‘Sutherlandia: miracle herb or poison?’ News of the clinical trials was similarly met with mixed and ambiguous responses. A professional body for doctors lauded this as scientific progress, but simultaneously added that they had collected abundant testimonies that traditional healers use human body parts in herbal mixtures. An activist non-governmental organisation that promotes access to and the use of antiretrovirals, the interests and rights of people who are HIV positive or are living with AIDS, expressed scepticism about Sutherlandia and its trials. A spokesperson correctly stated that all the pharmacological compounds in the plant is not yet known to science and warned against the use of plant medicines based in ‘belief’ rather than ‘fact’. An activist website raised questions about the close relationship between the promotion of traditional medicine,
funding for related research, Black Economic Empowerment, products developed from traditional medicines, as well as its registration. In a Faculty of Science a small group of senior academics opined that such trials do not fall into the knowledge domain of academic science. A spokesperson for traditional healers argued that the clinical trials are reductionist and not in accordance with indigenous cosmologies: only plants collected directly from nature can be utilised in healing. *Sutherlandia* represents many controversies surrounding knowledge and its practices. It is my belief that, at the heart of many of the controversies lies ‘the problem posed by any *pharmakon*’ (Stengers 2010): the lack of stable and firmly established characteristics or attributes.

In this paper I trace strategies to relate things, ideas, people, organisations, scientific publications etc. into a work-net that forms an apparent whole. I wish to emphasise the work done to stabilize some controversies surrounding *Sutherlandia*, traditional medicinal knowledge and clinical trials. Intensely polemical dualisms are understood as not fundamental but as enacted into being, as well as altered through, material-semiotic practices. The wider background is provided immediately below.

**Background**

**Indigenous knowledge and traditional medicines**

Why the concern with *Sutherlandia*, and with African traditional medicines for that matter? South Africa is a country with a high prevalence of HIV infected people and the government spends about R 8.8 billion a year on the cocktail of antiretrovirals for sufferers. Many South Africans use traditional medicines, including medicinal plants, singly or in a combination with other plants to deal with a variety of ailments. Numerous people do not get tested for HIV, but seek treatment through all kinds of Healers. Anecdotal evidence seems to indicate that some people use ARVs in combination with plant medicines.

Former President Mbeki’s envisaged African renaissance and the florescence of a post-apartheid intellectual agenda for the country, generated increased interest in African traditional medicines and brought about many developments. In 1997 the South African Traditional Medicines Research Group (SATMeRG) was established at the University of the Western Cape with funding from the Medical Research Council. It also linked UWC to the medical schools of the University of Cape Town with the aim of advancing traditional medicines and brought about many developments. In 1997 the South African Traditional Medicines Research Group (SATMeRG) was established at the University of the Western Cape with funding from the Medical Research Council (MRC) and the World Health Organisation (WHO). The aim was to study and evaluate African traditional medicines and explore their potential for bioprospecting. South Africa was and is touted as a potential medicinal treasure chest, both in terms of diversity and economic potential - with many plants of which the secrets should be unlocked through science.

A National Indigenous Knowledge Systems Office, with the task of co-ordinating national research on indigenous knowledge, was created within the Department of Science and Technology. The IKS policy has African traditional medicine as one of its particular foci and a Research Chair of Indigenous Health Care Systems, funded by the National Research Foundation, was established at the Nelson Mandela School of Medicine, University of Kwazulu-Natal. The Chair serves on the Presidential Task team on Traditional Medicines and a chair of the Traditional Medicines Research Platform and expert committee of the Department of Science & Technology on bioprospecting, as well as the WHO (Afro) expert committee on Traditional Medicine. The Medical Research Council established an Indigenous Knowledge Systems (Health) Lead programme with an IKS Resource Center and laboratories in Delft aimed to prioritise research concerning traditional medical knowledge, which had been historically neglected. New alliances were being forged and entities mobilized in the constitution of an economy, but also a science of traditional medicine. It opposed, and sometimes intertwined science and indigenous knowledge in intricate ways.

‘Traditionally’ used plant medicines are seen as vehicles for the promotion of health, but equally as assets in the national, and perhaps even the global economy (Reihling 2008). In this regard, South Africa’s national drug policy stresses the need to investigate traditional medicines as potential treatment for a variety of conditions of ill health. South Africa offers a rich potential base for the discovery of plant-derived medicines that will assist to fight HIV, tuberculosis, malaria etc. This is partially because many drugs available today originated in plants, e.g. the active ingredient, salicin, was extracted from willow tree bark until scientist were able to synthesize the drug chemically and created Aspirin. The opium poppy, *Papaver somniferum*, was, in time, studied in the laboratory to isolate the compound morphine and eventually derivatives were synthesized to make medicinal drugs.

The focus on traditional medicines also links to the World Health Organization and its efforts to promote traditional medicines though national policy and regulatory frameworks. In the case of South Africa such frameworks include the Traditional Medicines Draft Policy (2008), Medicines and Related Substances Control Act 101
of 1965, as amended (72 of 2008), and changes in the regulatory body, the Medicines Control Council. In the past plant medicines or phytomedicines were not registered with the South African Medicines Control Council, but under the current legislation, they have to be. The regulatory frameworks would, in many ways, be an effect of the clinical trials on Sutherlandia. The above developments are thus equally related to yet another WHO priority, namely the regulation of traditional medicine in terms of safety, efficacy and quality.

**Pharmakon**

The certainty of pharmaceuticals

The Greek word *pharmakon* can mean medicine, remedy or poison. It is the etymological root for pharmaceutical. Any pharmaceutical drug, or a medicinal plant for that matter, is potentially ambiguous – it can treat, give relief, heal, but can also be harmful, even toxic, especially if used incorrectly or in excess. This is the case for both plant medicines and pharmaceuticals: a study of acute poisoning cases treated at a selection of hospital in South Africa, showed that 2.4% related to traditional medicine, 0.2% to plants and 17.5% was caused by modern medicines (Malungu and Ogyynbanjo 2005).

Antiretrovirals represent the baseline treatment for people with HIV. ARVs are performed in media, information sheets, peer support groups etc. as factual: rational, safe, tested and efficacious. Yet, like all drugs, antiretrovirals are not harmless, and can have potential side-effects. Much of Mbeki’s opposition related to this aspect of antiretrovirals and as intimated by Green (2008b, 2009), Mbeki’s alleged AIDS denialism as well as the support of the former Minister of Health, Dr Tshabalala Msimang, for traditional medicines to treat people with HIV contributed greatly to the subsequent positioning of plant medicines as grounded in culture and belief and as ‘other’ to antiretrovirals. The scientific community was apparently disturbed when, in an address to the Presidential Task Team on African Traditional Medicine, Tshabalala Msimang warned against getting enamoured of western models and protocols for research and development of traditional medicines, e.g. through clinical trials.

Some ARVs, when used in combination therapy, interact with each other, as well as with other medicines. In a small number of cases ARVs can cause Immune Reconstitution Inflammatory Syndrome, a life threatening condition. Long-term use of ARVs can possibly cause irreparable damage such as peripheral neuropathy (nerve damage) and lipodystrophy (fat redistribution) (Cocohoba 2008).

In the literature and scientific papers the danger or problem of other medicines that interact with ARVs (and not vice versa) is stressed. Such drug-drug interaction is also investigated in clinical trials, reported and distributed in the scientific and health care community, as well as by advocacy groups. In health care settings and in advocacy groups ARVs are always enacted as remedial. It is science and savior rolled in one. The need to adhere to antiretroviral treatment regimens, and the necessity to never mix it with traditional plant medicines are strictly reinforced in support groups for patients (Mfecane 2011).

Nonetheless, antiretrovirals are very efficacious: they are proven to prolong the lives of people with HIV. They are used all over the world for patients, are almost continuously subjected to all kinds of clinical trials. They have followed the ‘normal’ route of drug discovery and development, involving the identification of molecular candidates such as antiretrovirals: i.e. a substance or substances that destroy or curb the growth of retroviruses, its synthesis, characterization, screening, and assays for therapeutic efficacy. Once a compound has shown its value in these tests, it will begin the process of drug development prior to clinical trials. In the scientific model of the development of medicines new compounds or molecular entities emerge from research. A good part of drug development involves the study and assessment of toxicity, pharmacokinetics and metabolism in humans prior to clinical trials. Another objective is to recommend the dosage and schedule for the first use in humans in a clinical trial. Entities, such as ARVs, must show possibilities against a specific disease entities, such as retroviruses. An example is the Phase III clinical trial, FACTS001, a large study of the ARV based microbicide Tenofovir gel in South Africa that is funded by the South African Government, in partnership with the US. Such a trial makes a certain reality: that of evidence based medicine and science.

In South Africa ARVs are performed as scientific. They are also deeply politicized and in the local science wars (Latour 1999) iconoclasts have cast scientific and ‘other’ knowledges, such as traditional medicine, across divides which sometimes seems insurmountable, with science represented as a positivistic, methodological testing for true knowledge and facts about the universe (Geffen 2010). Historically contingent conjectures are performed as objective reality (Barry 2006). I am, however, not concerned with the internal justification regimes of the science of antiretrovirals, but rather the ways in which its scientific practice functions to invalidate other knowledge practices that can impinge on HIV treatment, such as plant medicines.

The ambiguity of traditional plant medicines

The above counterposes healing pluralism in South Africa. The latter includes the frequent use of traditional medicines, which are done as vitalistic (Coulter and Willis 2004), not only aimed at physiological well-being and restoration of health, but also at spiritual, mental and communal harmony and cadences which not only involve the living but also ‘the living-dead ancestors and even the as yet unborn’ (Tangwa 2007:43). There are thus competing versions of reality: the scientific and pharmaceutical, the clinical, and
the traditional (Iyioha 2011). For science, the last is seen as the projection of belief onto an object, i.e. the plant medicine. The first is realised as autonomous and unconstructed, the factual. For traditional healers, the belief is real, it is ontological. Nevertheless, traditional medicine creates anxiety and should be stabilised for the purposes of running a clinical trial. One of the ways in which this is done is to stabilise it as a botanical entity.

In all scientific literature Sutherlandia is relationally performed as a botanical plant entity (van Wyk et al 2002) It is an indigenous shrub and traces its classification into a particular plant kingdom, sub-kingdom, division, class, order, family, and species etc. Sutherlandia grows in the Cape floristic region and is part of the fynbos biome and, botanically, it belongs to the class Magnoliopsida, order Fabales, genus Sutherlandia - but has been reclassified into Lessertia (Goldblatt & Manning 2000) - and species frutescens. Not all botanists are in agreement about this genus reclassification (van Wyk, Albrecht 2008) and, because the plant is so widely known under Sutherlandia, this nomenclature is far more commonly used. There are three related species of Sutherlandia (now Lessertia), S. tomentosa (reclassified as L. canescens), S. montana, and S. microphylla: all of these plants somewhat resemble each other and are hard to distinguish for the lay person. S. frutescens itself has six taxa or sub-groups, which are distinguished by habitat, orientation of its fruit stalk, form and downiness of its leaflets and shape of the pods (Iyioha 2009: 5). It has certain physical attributes: it is a small bush with bitter tasting greyish-green leaves, bunches of reddish butterfly-like flowers and large, bladder-like, papery inflated pods (Smith 1966; Roberts 1990; van Wyk et al 2002). The plant is part of the Cape floristic kingdom, the smallest and richest plant kingdom in the world (Xaba & Notten 2003). Despite the name change, Sutherlandia is clear, straightforward and outside time as a botanical entity. It has evolved as part of a particular plant kingdom over millennia. In this way Sutherlandia is performed as a specific natural plant entity ‘out there’ in nature. Although there are different names for the plant in the local languages, it is nonetheless classified and scientifically enacted as a specific species in the clinical trials, and thus as distinguishable from other plants and from other life forms. It is Sutherlandia whether it is in a flower pot, in a garden, sold as a dried flower, eaten by sheep or springbok, whether it is fresh, mashed, dried or powdered, ingested as a decoction or a capsule. Its scientific botanical description enacts it as universal factual knowledge whether the plant was used by San when the Dutch first learned about it from them around 1680, or when it is currently tested in a laboratory or in a clinical trial.

In Medicinal Plants of South Africa (2005), the volume most often referenced in relation to Sutherlandia, referred to the volume as ‘folklore’ turned into an ‘ethnomedicinal catalogue’, i.e. from a shifting frame of reference to a stable one. The ‘cultural’ information is treated as background to the true facts about Sutherlandia. The reported historical medicinal use of the plant brought it into clinical trials. From a pharmacological point of view the multiple uses of the plant is an advantage: it is an indicator that it potentially has medicinal value and Sutherlandia was consequently selected for testing as an African traditional medicine in clinical trials. To do so it has to pass through laboratories and clinical settings to be defined as a particular plant medicine.

In supporting documents related to the trials, it is emphasised that the plant was identified by a botanist, even though the plant material used in the capsules come from four farms in the Northern Cape, where they are cultivated for sale as Sutherlandia frutescens. To do clinical trials, a sufficient and reliable amount of plant material needs to be available for the duration of the trials. The quality of the plant material also needs to be controlled throughout the trials. Product (i.e. plant material) quality is critical in translating the plant medicine from nature to the regulatory necessities set out by the Medicines Control Council as authority which provides final ethical clearance and makes the trials possible. The correct identification of the plant as product is equally vital.

For evidentiary purposes it is performed as a botanical entity. This overlaps with the medicinal properties of the plant, as reported both in the book, and also in the documentation of the trials. The pharmacokinetics of Sutherlandia has not yet been fully explored, but it is known that principal active constituents include pinitol (a compound with anti-diabetic properties), canavanine (which increases appetite) and the amino acid GABA, (which produces a feeling of wellbeing) and asparagine. A novel triterpenoid glucoside has also been isolated and characterized in the plant (van Wyk, Albrecht 2008). Phytochemical investigations of the leaves have also lead to the isolation of four new 3-hydroxy-3-methylglutaroyl-containing glucosides, Sutherlandins A-D. The plant is tested as a phytomedicine, which is also the way in which it is used by the majority of people. Rather than focus on the individual compounds (all of which have
not been identified yet), the concern is rather with the synergy between the compounds in the medicine as a whole. It is theorized that the whole plant acts as a broad spectrum adaptogen which increases the body's resistance. *Sutherlandia* relates, in the broadest sense, to complementary and alternative medicine. It is also a traditional medicine. The trials are aimed at engaging with this plant medicine holistically, yet as a single botanical entity. While performing a generic definition it simultaneously brings it into existence as new hybrid knowledge.

Inconclusives

In the struggle for care for people who live with AIDS or chronic diseases, traditional medicine, like *Sutherlandia frutescens* is cast into, what is popularly called the treatment gap, i.e. for people who are HIV positive but whose CD4 counts do not make them eligible for ARVs. *Sutherlandia* is seen as a plant that can potentially be used to increase the time-span between being diagnosed as HIV-positive and having to go on ARVs. At the same time, the testing of a plant can be seen as a dislocation from the embodied knowledge practices of the traditional health practitioners. Such epistemological issues have been discussed by Oloyede (2010). Tangwa (2007), for example, argues that African traditional medicine do not have to be submitted to scientific trials because local people, who are also the holders of indigenous knowledge, are often familiar with traditional medicine and frequently use it themselves whilst consultations with healers are done in the open with no secrecy: i.e. in opposition to Western biomedical norms of clinical trials or of 'confidentiality'. But the issue is far more ambiguous and the hybrid science of an African medicine is in its infancy.

In terms of actor-network theory, such work-nets are not necessarily stable and need to be made and re-made all the time. If some of the elements, e.g. the administrative structure, the laboratories, the institutional support are not regularly ‘performed’ the work-net may be impacted. The relations brought into being are also not always smooth but can be full of conflict and can even become incompatible, adversarial and may even collapse.

Latour (1999) proposes that, rather than become embroiled in contestations about facts and beliefs, such as often happens in the case of *Sutherlandia*, as described above, we could attend to associations between humans and nonhumans and decline the antagonism between, e.g. subject/object, epistemology/ontology, belief/science and nature/culture. This may be a good starting point for unraveling the making of an African medicine, *Sutherlandia*.

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Endnotes

1. Ngwelezane hospital and a municipal clinic in Richards Bay
2. Prof Q. Johnson, former Director of South African Herbal Science and Medicines Institute, University of the Western Cape. Director of The International Centre for Indigenous Phytotherapy Studies (TICIPS)
3. 2004, See Green 2007, 2008 a,b, 2009 for and extensive discussion on IKS.

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