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Re-framing “counterfeit from a public health perspective”: A case for fraudulent medicine

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Abstract

“Black market” counterfeiters operating outside of authorised industry are often framed as the perpetrators of dangerous and defective medicines within legal pharmaceutical markets. However the assumption that all medicines which deliberately violate regulatory standards and quality specifications have black market origins is ill conceived, as poor medicine quality can occur regardless of who the manufacturer of the medicine may be. This paper proposes a reframing of all pharmaceutical products which intentionally, or negligently, fail to comply with regulatory standards and which are then fraudulently depicted as being *of* standard, from “counterfeit” to “fraudulent medicines”. This proposal is reinforced with examples from Australian law, where Australian pharmaceutical companies, who deliberately violated regulatory standards and produced defective and dangerous medicines, have been prosecuted using legislation designed to capture poor-quality, counterfeit drugs. The paper argues that these corporate crimes should not be framed as “counterfeiting” but as “frauds”, thus containing acts of “counterfeiting” to existing intellectual property (IP) law and providing due recognition for all acts which defraud and cause harm to the consumer.

Keywords

Counterfeit medicine, fraudulent medicine, medicine fraud, intellectual property (IP), public interest, IP maximalism.

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Introduction

Counterfeit medicines are an increasing health and crime problem in the developing world (Dukes, Braithwaite, & Maloney, 2014). Counterfeits make up approximately 10% of all medicines within legal distribution around the globe; in developing countries, rates are greater than 30% (World Health Organization [WHO], 2012). Some sources report rates as high as 90% in some developing countries, and estimate that deaths as a result of counterfeit medicines are

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likely to be in the hundreds of thousands each year (Pitts, 2006; WHO, 2003). Unsurprisingly, much of the literature in this area has focused on the victimisation of consumers and the negative consequences of consumption (Armengod & Baudenbacher, 2009; Attaran et al., 2012; Bate, Hess, Brush, & Malaria, 2009), and thus criminalises “black market” counterfeiters as *the* culpable “others” and *the* purveyors of dangerous and defective medicine within legal pharmaceutical markets (Bate & Boateng, 2007; Liang, 2006).

Yet the ways in which crime and criminalisation are defined within the literature, and by extension the state, can be fundamentally distorted (Pearce, 1973 & 1976). For instance, many developed countries remain relatively unaffected by the issue of counterfeiting (WHO, 2003 & 2012). We also find that in developed countries, crimes of the pharmaceutical industry have been on the increase (Dukes et al., 2014). And while counterfeit medicines are less of a problem for Australia—counterfeits make up less than one percent of the medicines within Australian legal supplies (WHO, 2012)—Australia has by no means been immune to the issue of poor quality and fraudulent medicines. The many crimes of the Australian pharmaceutical industry over the past decade have been documented in numerous cases (Department of Health and Aging (DoHA), 2003; *R v Comax-Pharma Pty Ltd*, 2008; *R v Pan Pharmaceuticals Pty Ltd*, 2008; *Secretary, Dept of Health and Aging v Prime Nature Prize Pty Ltd (in liq)*, 2010), and scholarly sources (Faunce, Urbas, & Skillen, 2011; Faunce, Urbas, Skillen, & Smith, 2010). In developed countries such as the United States (US), deaths as a result of the frauds and malpractices of the pharmaceutical industry far outweigh those rates recorded for murder and manslaughter combined (Dukes et al., 2014).

We therefore argue that it is ill conceived to assume that the failure to comply with good manufacturing practices and quality specifications is limited to non-authorized manufacturers, and that corporate non-compliance with such standards cannot be a result of ‘deliberate causes’—a fact which is ‘often ignored or underestimated’ within the academic literature (Cauldron et al., 2008, p. 1063). Central to this often overlooked criminological issue is the need to acknowledge that the frauds and malpractices of pharmaceutical companies also leads to a violation of regulatory standards, and the production of poor quality and fraudulent medicines. This paper therefore distances itself from the criminalisation angle embraced by recent literature which frames black market counterfeiters as the culpable ‘others’. Instead, this paper focuses on those harms experienced by individual consumers as a result of the malpractices and frauds of the pharmaceutical industry; an issue which has been under discussed, if not neglected by, the academic literature.²

Tension exists for counterfeit medicines—one of many types of poor quality and fraudulent medicine in circulation—due to a conflict between IP enforcement and public health protection. Unlike other commonly counterfeited items, a counterfeit drug not only infringes upon IP rights, but is also capable of causing physical harm. However in current definitions for counterfeit medicines, the counterfeiting aspects of these offences (the misrepresentation of the goodwill and reputation of the rights holder) are not made distinct from those aspects which also makes

² Beyond notable exceptions, including Reiman and Leighton (2009) and Dukes et al. (2014).

these medicines “fraudulent” to the consumer (the deliberate misrepresentation of the good which leads one party to dishonestly “gain” over another). The failure to distinguish between the two interest issues impacted by counterfeiting (private and public) has caused conflict at the international level in developing an exact definition for counterfeit medicines. “Counterfeit” therefore remains a conceptually vague term within both legislation and the academic literature, and many poor quality and fraudulent medicines are often mislabelled as “counterfeit” as a result.

This paper highlights the consequences of this lack of clarity by providing examples from Australian law. These case studies demonstrate instances where legislation designed to capture poor-quality, counterfeit medicines has been used to prosecute Australian pharmaceutical companies for the intentional production of non-compliant and fraudulent medicines. We propose to reconceptualise these drug misrepresentations experienced by consumers as “fraudulent medicine” and “medicine fraud” rather than as counterfeit medicines, so as to frame the harms caused by intentionally (or negligently) non-compliant and fraudulent medicinal products in much clearer terms. Adopting a term like “fraudulent medicine” to categorise *all* medicines which deliberately violate regulatory standards and quality specifications, regardless of the type of manufacturer, would allow acts of counterfeiting (violations of private rights) to be contained to existing IP law and would provide due recognition to those acts which defraud and cause harm to the end-consumer. As a consequence of this reframing, victims would have much clearer and tested protection from the state, while also allowing for the punishment of companies—and by extension, black market medicine counterfeiters—beyond the strict limits imposed by current criminal laws. This would also serve the purpose of clarifying the misconceptions the term “counterfeit” has generated within the literature and beyond by centring the responsibility for IP enforcement with pharmaceutical companies.

This paper explores these issues in three parts. Part One re-conceptualises the term counterfeit medicine to make clear the distinction between the private and the public interest issues impacted by the offence. Part Two examines the ways in which counterfeit medicines are currently defined within the international space and in particular, how a lack of consensus in defining the issue at the international level has given rise to the conceptual problems inherent to most present day definitions. This section begins by evaluating the definition developed by the World Health Organization in 1992, and the difficulties WHO has since faced in attempting to frame drug counterfeiting as a public health-only issue. Part Three will in turn examine how counterfeit medicines are defined within Australian law and under the *Therapeutic Goods Act 1989* (Cth). Selected case studies, which include Curacel International, Pan Pharmaceuticals, Comax-Pharma, and Prime Nature Prize, are provided to demonstrate the net-widening effect of the current definition and thus, its ability to misconstrue true rates of criminal counterfeiting *and* corporate crime in the Australian pharmaceutical industry.

Part one: A conceptual breakdown of the offence of counterfeiting within the IP context

It is important to emphasise here that ‘[e]xact definitions in this field are of crucial importance’, as previous attempts by the research-based pharmaceutical industry to curb the trade of

counterfeit medicines, while often well intentioned, are at times ‘too closely linked to its more controversial efforts to counter the trade in genuine generic drugs’ (Dukes et al., 2014, p. 202). It is these conflicts surrounding IP enforcement which have undermined the ability of the international community to reach a consensus on a precise definition for counterfeit medicines (Dukes et al., 2014).

Traditionally, international law has recognised counterfeiting as the unauthorised use and misuse of a trademark or trade name,³ a patent violation, or as an act of “passing off”⁴ when grounds for trademark infringement cannot be established. Legal action against trademark violators intends to resolve any private disadvantage (the misrepresentation or damage of the goodwill of the trader) and not the public deception and physical harms experienced by the consumer as a result of a false and misleading representation. This is because:

[t]he logic behind criminal sanctions for wilful and commercial counterfeiting ... derives from analogy with theft of physical property. It is not in any way related to the harm that might be caused by consuming such goods, or concerns about the quality of such goods (Clift, 2010, p. 7).

Addressing the conceptual legal problems surrounding the framing of counterfeit medicines will allow us to distinguish between the two different interest issues directly impacted by medicinal counterfeiting, the private rights of companies and the greater public-health interest. In failing to distinguish between these two interest issues, pharmaceutical companies are often framed as the collective victims due to the significant amounts of revenue loss experienced as a result of the IP infringement (Bird, 2007-2008). This view is reflected in the academic literature; many authors note the financial burdens (Moken, 2003; Noon, 2009), as well as the impacts on brand names which come to be associated with ineffective counterfeit medical products (Chakraborty, Allred, & Bristol, 1996; Gilbert, Walley, & New, 2000; Moken, 2003). Paradoxically, the blame for the counterfeit market’s success largely falls on consumers—those individuals who continue to purchase the wrong products from the wrong people, particularly internet pharmacies, and therefore feed the market’s growth (Bird, 2007-2008; Mackenzie, 2010). Law enforcers are also regularly considered at fault for the poor regulation and inconsistent policing of the issue at both the national and international levels (Mackenzie, 2010).

However, not all costs associated with business activity are borne by the corporation, and ultimately such costs are assumed by society—what the literature refers to as “negative externalities” (Mackenzie, 2010; Tombs & Whyte, 2015). IP enforcement is one such externality; counterfeiting and piracy offences are often portrayed by companies as forms of crime rather than a direct outcome of market production, and corporate merchandising and branding activities (Mackenzie 2010). The framing of counterfeits as criminal, rather than a

³ Defined here as ‘any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation’ (*TRIPS Agreement 1994*, s. 14.a.).

⁴ Passing off concerns ‘the misrepresentations made by one trader which damage the goodwill of another’ (Wadlow, 1990, p. 10). In the extension of the tort, “passing off” can also involve misrepresentations by the defendant of the quality of the plaintiffs goods (Davis, 2007).

predictable consequence of capitalist markets, has permitted the responsibility of enforcement to be deflected onto law enforcement agencies (to expend the costs and resources to enforce the law), and any potential risks and harms to be socialised onto consumers. According to Mackenzie (2010), industry should therefore take ownership of its negative externalities alongside any positive externalities. To some extent, pharmaceutical companies and manufacturers are liable for any injuries caused by counterfeit medicines should they fail to employ the appropriate safeguards for their products (for example, by way of widely available “track and trace” technologies) (Feldman Aleong, 2007). The onus should therefore be on pharmaceutical companies to employ the appropriate mechanisms to safeguard their products from counterfeiting. Companies which fail to accommodate for the costs associated with IP protection and enforcement, not only must accept the potential consequences this poses to their own products, but also the given level of risk this creates to the public.

Re-conceptualising the offence of medicine counterfeiting

Research has consistently demonstrated that the vast majority of medicines found to infringe upon IP rights either contain lesser amounts of the active ingredient or no active ingredient at all when compared to the genuine product (Almuzaini, Sammons, & Choonara, 2013; Bate, Zhe Jin, & Mathur, 2012). There have also been numerous findings of counterfeit medicine containing contaminants (Polgreen, 2009) and undeclared substitute ingredients (Chaubey, Sangla, Suthaharan, & Tan, 2010), which can put the consumer at significant risk. Despite the idea of a “perfect clone” being theoretically plausible, in reality ‘the motivation for counterfeiters is short-term profits, not reliable products with sustained repeat business’, and as a result, ‘[m]ost illegal drug manufacturers are more inclined to perfect the packaging of their products [rather] than the contents’ (Bate, 2012, p. 29).

The lesser told story however, is that pharmaceutical companies may also produce substandard and harmful products in defiance of legal and regulatory regimes. In both cases, the actions of the illegal and legal drug manufacturers clearly amount to “fraud” since medicine quality is not being replicated to the same standard of the genuine product—instead, product quality is intentionally or negligently compromised and then deliberately concealed from the consumer by these manufacturers. Should a “perfect clone” be created by an illegal manufacturer and the product comply with the regulatory requirements for quality, safety and efficacy, we would argue that such goods are “counterfeit” since they only cause harm to the rights holder and not the general public. “Imperfect clones” would therefore be classed as both “fraudulent” and “counterfeit”, and should be prosecuted under separate pieces of legislation.

Two different forms of product misrepresentation therefore occur as a result of medicine counterfeiting, each of them having consequences for two very different types of victims.

Firstly, counterfeit medicines involve a misrepresentation of the goodwill and reputation of the rights holder, in this case the pharmaceutical company. These medicines are forgeries, copies and imitations which are presented as the genuine product with the aim of capitalising financially on the goodwill and reputation of the rights holder, for example, by replicating trademarks or trade names, by infringing patents, or by “passing off” the product as the genuine item. These medicines therefore fall within the framework of IP law and “counterfeiting” for the purpose of remedying any private disadvantage within the market.

Secondly, medicine counterfeiting involves another form of misrepresentation which falls within the much wider category of fraud. These frauds occur as a result of a false representation or a deliberate concealment of material facts regarding the good, which, during the course of a transaction, results in one party dishonestly obtaining a “gain” over another. Here, the party in direct receipt of the goods, the end-consumer, is the clearly identifiable victim, and any deliberately false, misleading or deceptive claims regarding the product, which prompted the purchase of the good, is the subject of the offence. A clear example of this second form of misrepresentation is the deliberate concealment of the product’s quality from the consumer: the medicine claims or gives the impression that it is of an appropriate quality or standard, via its labelling, presentation, advertising or medicine information (compendium), when it is actually of a poorer quality or standard, as a result of intent or negligence.

Given this re-conceptualisation of the offence, we advocate that “fraudulent medicines” and “medicine fraud” would be a more appropriate terminology for framing the types of misrepresentations being experienced by the consumer, rather than the term “counterfeit medicines”. This re-conceptualisation would also place responsibility for the enforcement of the “counterfeiting” aspects of the offence squarely upon the pharmaceutical company.

The Case for “Fraud”

Attaran and his colleagues argue that ‘[d]eliberate counterfeiting is a private economic wrong, which can occur separately from or together with the public health wrong of poor medicine quality’ and that ‘it is a mistake ... to use the adjective “counterfeit” to refer to medicines that endanger public health’ (Attaran et al., 2012, p. 2). Attaran et al. (2012, p. 2) use the term “falsified medicine” to refer to the public health aspects of the crime, and the intentional failure to meet legally required quality standards established by a regulatory authority. By adopting this new label, Attaran et al. (2012) have been able to reserve the term “counterfeit” exclusively for private rights violations. This terminology and description has since been embraced by a small number of authors (Almuzaini et al., 2013; Taberner, Fernández, Green, Guerin, & Newton, 2014), but the vast majority of academics continue to use the term “counterfeit” medicines.

Although we agree with this differentiation of interest issues, we prefer the term “fraudulent” over the term “falsified”. “Falsified” is already widely used within the academic literature and national legislation in reference to both public and private interest issues. “Falsified” is also sometimes used interchangeably and synonymously with the term “counterfeit” (see Bate, 2012, p. 28), and therefore a different terminology is warranted to prevent the ongoing confusion of the terms.⁵

⁵ It is worth noting that some legal definitions also attempt to separate IP violations from the public health aspects associated with the offence. US federal legislation for example, uses the term “adulterated drug”. Section 501(b) of the *Food, Drug, and Cosmetic Act 1938* (US) classifies a drug as adulterated when it fails to conform to compendial standards of quality, strength or purity. This includes medicines: which contain ‘filthy, putrid, or decomposed’ substances; that are packed, held or prepared in unsanitary conditions (which may render the product contaminated or injurious to health); where the methods, facilities or controls used for the manufacture, processing, packing, or holding of the medicine do not conform to nationally recognised standards; and where drug testing methods do not conform with nationally recognised standards (*Food, Drug, and Cosmetic Act 1938* (US), at 21

Confusion of these two interest issues has been more easily avoided by adopting the term “fraud” in other product sectors. In the food arena for instance, ‘the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging, or false or misleading statements made about a product, for economic gain’ is framed as “food fraud” (Salinger, 2013, p. 346). The term is used collectively to encompass a variety of crimes which are perpetrated against the consumer (the adulteration, tampering, and misbranding of foods), as well as for those acts committed against companies (the overrunning, stealing, diverting, smuggling, and counterfeiting⁶ of products) (Salinger, 2013). Food frauds are also acknowledged as a form of white-collar and corporate crime, as well as organised crimes (Johnson, 2014; Salinger, 2013; Tombs & Whyte, 2015). As a consequence of this framing, prosecutions can be carried out under separate pieces of legislation to cater for each type of victim.⁷ This is in stark contrast to the pharmaceutical sector where “counterfeit” is the preferred label for all deliberately defective and fraudulent medicine.

Part two: Counterfeit medicines within the international context

Part of the problem in re-conceptualising the issue of counterfeit medicines derives from the lack of consensus on a fully agreed upon international definition, which has led to a diverse range of definitions being adopted at the national level.

The definition produced by the World Health Organization is the most cited one within the academic literature and was the first developed at the international level. The WHO definition was initially conceived during a workshop held in 1992 by the WHO and the International Federation of Pharmaceutical Manufacturers’ Associations (IFPMA) (WHO, 1992). As a result of the workshop, a counterfeit medicine definition was established as the following:

A counterfeit medicine is one which is deliberately and fraudulently mislabeled with

U.S.C 321 §501). Again, however, “adulterated” suffers the same issues as the term “falsified” in that it is often used synonymously with “counterfeit”.

⁶ In the United States, a Food and Drug Administration (FDA) working definition defines food fraud (which they also refer to as economically motivated adulteration or EMA), as the:

fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain. EMA includes dilution of products with increased quantities of an already-present substance ... to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution (FDA, 2009; as cited in Johnson, 2014, p. 5).

Food fraud is framed as a form of deception which results in the physical or financial harm of the consumer due to the non-disclosure or misrepresentation of information. This conceptualisation does not include any vague or subtle references to misrepresentations of trademark identity or patent source, but would include instances of deliberate misdescription of a food’s content (identity) or source of origin.

⁷ In the United States, food frauds against consumers are covered under the *Food Safety and Modernization Act 2011* (US), which is administered by the FDA (Salinger, 2013). The IP aspects of food fraud which result in the misrepresentation and defrauding of the corporation, are captured under separate legislation, the *Protect Intellectual Property Act 2008* (US), and are privately enforced (Salinger, 2013).

respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging (WHO, 1992, p. 1).

This definition has since been influential on government policy and legislation globally, with many aspects of the WHO definition having been incorporated into national legislation (see Preliminary Draft Survey on National Legislation on “Counterfeit Medicines”, WHO, 2010). However the unresolved private interest issues which underlie this current definition have led to the emergence of three notable criticisms.

Firstly, the lack of clarification surrounding terms such as “identity” and “source”, which bear connections to the IP concepts of trademark infringement and “passing off”, has led to the assumption that IP rights are at the forefront of counterfeit drug enforcement under such definitions. “Identity”, for example, could ‘refer to [the] trademark or the trade name of the drug, which means that a drug of good quality but having a close similarity with another trademark or trade name can be termed as a counterfeit drug ... [and] “source” could be interpreted to mean the patent holder of that product or the chemical entity’ (Shashikant, 2009, pa. 33). As trademarks and patents are an indicator of the identity and origin of a good or service, these aspects of the WHO definition overlap with IP laws (Lieberman, 2012). This has led sceptics to argue that in the first instance, the WHO might be advocating for the enforcement of IP rights, rather than the public health mandate (Shashikant, 2009).

Secondly, the use of the term “counterfeit” draws criticism because of the term’s explicit use in IP law (Attaran et al., 2012). A number of nation-states argue that the term’s use should be restricted to violations of private property rights only, and not quality, safety and efficacy issues. Japan, Morocco and South Africa are some of the few WHO member states that use the term “counterfeit” specifically in reference to IP violations (WHO, 2010). Yet, only 4% of the 70 WHO member states surveyed (there are 194 WHO members in total) appear to use the term in this manner, with the vast majority of member-states using “counterfeit” in ways which resonate with the WHO definition⁸ (WHO, 2010). Some regional groups, the EU and Latin America in particular (see Clift, 2010), have adopted the terms “falsified”, “fake” or “spurious” as a way of distancing the definitions away from “counterfeit” and IP law. However, even with such changes, the definitions continue to suffer from similar controversies as the WHO definition in that the language used still alludes to IP issues.⁹

And thirdly, the WHO definition is problematic because it acknowledges the public interest aspects of counterfeiting offences whilst also drawing connections to private interest issues and IP law. Again, this is because counterfeiting (IP) is not being made distinct from those aspects of the offence which makes these medicines “fraudulent” to consumers. The WHO definition attempts to acknowledge these public interest aspects by trying to frame drug quality as *the* issue,

⁸ Many of the legal definitions contained the same terminology and qualifiers as the WHO definition. See pages 6 to 12 of the WHO (2010) for a further explanation, and *Table 1* on page 10 of the same document for an overview of the initial findings.

⁹ Simply substituting “falsified” in place of “counterfeit” is also not justified when there are in existence products which clearly infringe upon private rights and violate pre-existing IP laws.

but the definition can be ambiguous in its application since the consumer is not the clearly identifiable sole victim. The confusion of the WHO in distinguishing between these two interest issues is clearly visible in the WHO quote below:

[f]alsified or counterfeit medical products may infringe intellectual property rights, but whether a good is considered counterfeit from a public health perspective is independent of whether the product infringes intellectual property rights (WHO Secretariat 2010; as cited in Clift, 2010).

Little clarification has been provided by the WHO as to what “counterfeit from a public health perspective” means, and how a counterfeit medicine would, in this respect, differ from any other form of defective medicine which falsely purports to do something it cannot (Clift, 2010). As a result of this lack of clarity and direction at the international level, the term “counterfeit” is used across a variety of contexts to refer to activities of both private and public interest. In the United States for example, “counterfeit” is used in specific reference to IP violations within federal legislation,¹⁰ but the national regulatory authority, the Food and Drug Administration (FDA), uses the term in the same broad context as the WHO (FDA, 2014). The lack of consensus on this definition has not only led to inconsistencies in the enforcement of the issue, but also in measuring the scale of the issue; a large proportion of poor quality medicines are often classed as “counterfeit” even if it is unclear as to whether they were produced fraudulently or as a result of poor quality control or manufacturing practice by authorised industry (Newton et al., 2011).

The International Medical Products Anti-Counterfeiting Taskforce (referred to as IMPACT, 2008, p. 4) has since revised the WHO definition to include additional provisions, such as the statement, ‘[v]iolations or disputes concerning patents must not be confused with counterfeiting of medical products’. These revisions do not exclude all forms of IP infringement from the definition entirely, only patent violations, and the definition continues to utilise the same loaded terminology, “identity” and “source”. Even more recently, the WHO adopted the broader label of spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines. However, this new label does not resolve the pre-existing issues surrounding the separation of interests. Instead, the label captures a wider range of deficiencies under the rubric “counterfeit”, making the term all the more conceptually vague.

Although the WHO may argue that IP concerns are not central to its definition, the WHO is not explicit in the fact that counterfeiting, in an IP sense, is something that can occur separately from or together with public interest issues and poor medicine quality (Attaran et al., 2012). Since the term “counterfeit” has a very specific meaning in IP and legal discourse, it cannot simply be repurposed, as has been done by the WHO, without always creating links with its original discourse.

Part three: The Australian context

¹⁰ According to the *Food, Drug, and Cosmetic Act 1938* (US), at 21 U.S.C 321 §201(2)(g)(2), 'The term "counterfeit drug" means a drug which, or the container or labelling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor'.

Medicinal counterfeiting is avidly portrayed in Australia as having “black market” origins and as occurring outside of Australian legitimate supply chains, only an posing issue for Australian consumers who travel and purchase medicines abroad or when making online purchases from rogue internet pharmacies (Therapeutic Goods Administration [TGA], 2011). However Australian anti-counterfeiting legislation has largely been used to prosecute the fraudulent activities of pharmaceutical companies (case studies one to four). Furthermore, Australian legislation has rarely been used in cases of public harms caused by black market counterfeiters operating outside the legitimate industry and for which the legislation was originally intended (case study five).

“Counterfeiting” under Australian legislation

Offences involving the false representation of a therapeutic good, regardless of whether this representation occurred as a result of recklessness or intent, are prosecuted as forms of counterfeiting under section 42E of the Australian *Therapeutic Goods Act 1989* (Cth) (see *Box 1*).

BOX 1: *Therapeutic Goods Act 1989*, Section 42E “Offences of dealing with counterfeit therapeutic goods”

- (1) A person is guilty of an offence if:
 - (a) the person intentionally:
 - (i) manufactures goods in Australia; or
 - (ii) supplies goods in Australia; or
 - (iii) imports goods into Australia; or
 - (iv) exports goods from Australia; and
 - (b) the goods are therapeutic goods; and
 - (c) the goods are counterfeit and the person knows that fact or is reckless as to whether that fact exists.

Penalty: 7 years imprisonment or 2,000 penalty units, or both.
- (2) Goods are ***counterfeit*** if any of the following contain a false representation of a matter listed in subsection (3):
 - (a) the label or presentation of the goods;
 - (b) any document or record relating to the goods or their manufacture;
 - (c) any advertisement for the goods.
- (3) The matters are as follows:
 - (a) the identity or name of the goods;
 - (b) the formulation, composition or design specification of the goods or of any ingredient or component of them;
 - (c) the presence or absence of any ingredient or component of the goods;
 - (d) the strength or size of the goods (other than the size of any pack in which the goods are contained);
 - (e) the strength or size of any ingredient or component of the goods;
 - (f) the sponsor, source, manufacturer or place of manufacture of the goods.
- (5) To avoid doubt, a term that is defined in subsection 3(1) in relation to therapeutic goods and used in this section in relation to goods has in this section the meaning given by subsection 3(1).

Prior to the creation of section 42E, false representations had to be prosecuted as the lesser offence of manufacturing, importing and exporting a therapeutic good not listed or registered on the Australian Register of Therapeutic Goods (ARTG) (Griffin, 2000). Approximately 20% of the 200 criminal charges laid under the Therapeutic Goods Act between 1991 and 1996 were a result of the exploitation of exportation standards by Australian licensed manufacturers and sponsors for goods not listed on the ARTG (Griffin, 2000; KPMG, 1997). The majority of these convictions against the Australian pharmaceutical companies were for the illegal export and sale of substandard and unregistered products to countries such as Malaysia, Vietnam, Singapore and New Guinea, where lower standards of pharmaceutical regulation, and less than adequate inspection and control mechanisms existed (Griffin, 2000). Section 42E therefore serves a dual purpose in Australia and is thus ‘very broad’ and ‘very strict’ in international terms (McEwen, 2007, p. 161). This often results in a wide variety of cases being prosecuted under section 42E, as briefly summarised below.

Case study one: Curacel International

In 2003, Curacel International, the first drug company in Australia to be charged under section

2008 at 27). An investigation of electronic batch records held by the company also revealed that on some occasions, the drug's potency levels did not fall within the specified pharmacopoeial limits (*R v Pan Pharmaceuticals Pty Ltd*, 2008 at 45). To ensure that the strength of the declared active ingredient fell within pharmacopoeial limits, and thus produced the "desired" results, drug potency tests were manipulated by Pan employees (*R v Pan Pharmaceuticals Pty Ltd*, 2008 at 45). This in turn led the packaging and drug specifications for each finished product to be incorrect.

In addition to knowingly using false documents (a violation of s. 145.1(5) of the *Criminal Code Act 1995* (Cth)), Pan was charged with the export and manufacture of "counterfeit medicines" on the basis that the certificates and batch records misrepresented the type of goods being manufactured and exported. The company was subsequently fined AU\$10 million (*R v Pan Pharmaceuticals Pty Ltd*, 2008 at 39).

Data manipulation was a widespread practice at Pan Pharmaceuticals (*R v Shayma Jain*, 2005 at 16), the most high profile incident being the manipulation of batch records for Travacalm, a travel sickness drug. Travacalm varied between 0 - 700% in strength due to the use of an unapproved (and less expensive) wet granulation method to mix the batches of product. The Australian TGA, the Australian drug and devices regulator, received a number of reports of adverse drug reactions from the use of Travacalm, of which 19 incidents resulted in the consumer being hospitalised (McDonald, 2008).

Case study three: Comax-Pharma

Similarly, Australian complementary medicines manufacturer Comax-Pharma was found to be involved in the manipulation of quality data in 2008. A batch of product, which received an initial fail rating during quality testing for containing amounts of raw material which exceeded quality standards, was deliberately substituted by Comax-Pharma staff with a batch that had been previously approved during the retesting phase, in order to gain approval to export the defective batch (*R v Comax-Pharma Pty Ltd*, 2008). Comax-Pharma were fined \$522,000 (*R v Comax-Pharma Pty Ltd*, 2008).

The company had been in liquidation and had ceased trading at the time of the trial (*R v Comax-Pharma Pty Ltd*, 2008), but was officially deregistered in 2013 (ASIC, 2015a).

Case study four: Prime Nature Prize (PNP)

The Australian company PNP was charged with multiple counterfeiting offences in 2010, ranging from the sale of unapproved products, the falsifying of the listing/registration of products, and the fabrication of certificates of manufacture. PNP was predominately engaged in the selling of complementary medicines and health food products to Korean visitors to Australia (*Secretary, Dept of Health and Aging v Prime Nature Prize Pty Ltd (in liq)*, 2010). This arrangement attracted 1,600 – 2,000 tourists to PNP per month, each of whom would spend on average AU\$400 – 500 during their visit to the PNP premises (*Secretary, Dept of Health and Aging v Prime Nature Prize Pty Ltd (in liq)*, 2010). The company's average annual turnover was

approximately AU\$14 million prior to the decline of its business in 2007, when the loss of contracts with travel agents saw fewer than 1,000 tourists visiting PNP each month (*Secretary, Dept of Health and Aging v Prime Nature Prize Pty Ltd (in liq)*, 2010).

In 2010, PNP was charged with counterfeiting under the *Therapeutic Goods Act 1989* when their product—OsteoMax-7—bore an ATGR listing number when it had not received market approval (*Secretary, Dept of Health and Aging v Prime Nature Prize Pty Ltd (in liq)*, 2010). The ATGR number had in fact belonged to a rival product, Four in One Joint, which was sponsored by another company, the Health Sharing Group (*Secretary, Dept of Health and Aging v Prime Nature Prize Pty Ltd (in liq)*, 2010). PNP had sponsored, and correctly listed, 7 other products on the ATGR prior to OsteoMax-7 and were therefore well aware of the procedures for product listing.

PNP was also found to have falsified the certificates of manufacture for the supplement Plamax (*Secretary, Dept of Health and Aging v Prime Nature Prize Pty Ltd (in liq)*, 2010). The certificate contained the listing number of a legitimate PNP product, known as Propolis (*Secretary, Dept of Health and Aging v Prime Nature Prize Pty Ltd (in liq)*, 2010). The certificate was also fabricated by altering the original Propolis certificate to read “Plamax”; Plamax was never actually approved for market (listed on the ARTG) (*Secretary, Dept of Health and Aging v Prime Nature Prize Pty Ltd (in liq)*, 2010). For supplying and manufacturing counterfeit goods, Prime Nature Prize was ordered to pay AU\$4,700,000 (*Secretary, Dept of Health and Aging v Prime Nature Prize Pty Ltd (in liq)*, 2010).

Case study five: Pfizer Australia and the Australian black market

In contrast with the incidences described above, there has been very little available information regarding the prosecution of black market counterfeiters in Australia. Only one incident where a black market counterfeit has infiltrated the legitimate pharmacy supply chain has ever been publicised.

In 2010, Pfizer Australia recalled 750 packets of Viagra purchased from pharmacies in New South Wales and Victoria which were found to contain the incorrect dose of the key ingredient, Sildenafil (Pfizer, 2010a, 2010b). Since the discovery of the counterfeit Viagra pills in pharmacies, no further information has been provided to the public (particularly whether any individuals were held to account). We contacted Pfizer at the time of the incident, but we did not receive a response. Pfizer Australia has since revealed that as many as 6,000 seizures of counterfeit Viagra have been made in Australia over the past decade (Duffy, 2014; Theriault, 2004), with many found to contain ‘paint, other toxins, heavy metals, chalk, rat poison, other liquids like anti-freeze [and] ink which would allow it to dissolve or mix’ (Duffy, 2014, pa. 19). Again, however, we find that little information was publically provided by the company about these incidences when they arose—if safety was truly paramount, access to risk-averse information and public follow up would have been made a priority by the company.

More recently, the Australian Therapeutic Goods Administration has published the outcomes of all decisions and actions carried out under the *Therapeutic Goods Act 1989* (Cth); the

information provided however, is extremely limited.¹¹ Based on this information, four men have been charged with counterfeiting offences over the 2013-2014 period, with penalties ranging from community service (350 hours) to AU\$2,000 in fines (TGA, 2015). In a personal communication with the Commonwealth Department of Public Prosecutions (DPP), it was confirmed that the DPP had conducted a further 18 prosecutions under section 42E between February 2003 and March 2013, 14 of which involved successful convictions. The majority of these cases appear to involve pharmaceutical companies, and their executives and employees.¹²

Conclusion

The Australian case studies demonstrate the need to re-conceptualise the issue of counterfeit medicines. It has been the lack of clarity and direction surrounding the definition of medicinal counterfeiting at the international level, along with the broad scope of the Australian legal definition, which has led to an acceptance that such acts are counterfeiting for legal purposes. This interpretation has misconstrued true rates of counterfeiting in Australia, and misrepresented the extent of corporate crime occurring within the Australian pharmaceutical industry.

Much of this confusion is a direct result of the failure to isolate the different interest issues impacted by counterfeit medicines. Pharmaceuticals however, are a highly profitable business, particularly in terms of the low costs of production and the high margins of profit generated by advertising and promotion (Hoe, Hogg, & Hart, 2003). Current crime prevention methods are therefore focused on curtailing the growth of counterfeit drug markets rather than removing the incentives to produce counterfeits at its primary source—at business level. The criminalisation of the parallel industry, through the adoption of definitions which promote an IP maximalist agenda, and the deflection of responsibility onto consumers, is not the solution. As the forum for a counterfeit industry continues to exist, counterfeit medicines will continue to be produced. IP infringements should therefore remain confined to IP law, and the issue of poor quality and fraudulent medicines redefined by adopting the term “fraudulent medicine”, to frame in much clearer terms that consumers are the true victims of product quality misrepresentations and frauds, not pharmaceutical companies.

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¹¹ This information appears on a general “court action” web-page along with criminal prosecutions against pharmaceutical companies. Court outcomes for counterfeiting offences are not listed separately. All names and information regarding the nature of the offences have been removed (see TGA, 2015).

¹² These include all but the civil case mentioned in Part Two of this paper. It is possible that one of these 14 cases may have involved a conviction for “black market” counterfeit drugs, however as no judgement was reported or information made available to the public, this assumption cannot be verified.

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