emerald hill associates
Corporate Advisory & Legal Services

Productivity Commission: Right To Repair Inquiry Submission on behalf of MD Solutions

Richard Dammery

INTRODUCTION

1. MDScopes (MDS) is a subsidiary of MD Solutions Australasia, a well-established and well-regarded supplier of medical devices. Established 26 years ago, MDSA plays an important role in introducing high quality surgical devices to Australasian surgeons and hospitals.

2. MDS welcomes the opportunity to make this submission to the Productivity Commission in relation to this important Inquiry. The focus of this submission is on unfair restrictions to repair in medical device aftermarkets in Australia. However, MDS has sought to respond to the Productivity Commission's other information requests as appropriate.

INFORMATION REQUEST 1: DEFINING RIGHT TO REPAIR

3. MDS notes that "right to repair" is likely to have different connotations in different industries and market segments. In the medical devices industry, MDS submits that "right to repair" implies that customers – generally medical practitioners, hospitals and clinics – should be able to seek cost efficient and safe repair of medical devices by suitably qualified technicians. MDS notes that, as outlined in this submission, there are currently a number of impediments to this occurring, largely due to the market power and conduct of Original Equipment Manufacturers (OEMs).

INFORMATION REQUEST 2: WHAT TYPES OF PRODUCTS/ PARTICULAR PRODUCTS?

4. MDS submits that the Productivity Commission should, amongst others, focus on medical devices markets, given the importance of the healthcare system to the Australian economy. Spending on health has grown in Australia by about 50% in real terms over the past decade, from $113 billion ($5,500 per person) in 2006–07 to $170 billion ($7,100 per person) in 2015–16. This compares with population growth of about 17% over the same period. Governments fund two-thirds (67%, or $115 billion) of all health spending, and non-government sources fund the rest (33%, or $56 billion). Individuals contribute more than half (17%, or $29 billion) of the non-government funding. Together, hospitals (39%) and primary health care (35%) account for three-quarters of all health spending. Companies

such as MDS have an important role to play in reducing health care costs, as well as introducing new and innovative medical device technologies into Australia. They should not be subject to restrictions of the type imposed by OEMs.

5. In this context, MDS submits that the Productivity Commission may find the market for medical scopes repair an interesting case-study.

6. Medical scopes are crucial in the diagnosis and cure of a range of medical conditions. Generically referred to as "Endoscopy", the use of scopes allows doctors to observe the inside of the body without performing major surgery. An endoscope is a long flexible tube with a lens at one end and a video camera at the other. The end with the lens is inserted into the patient. Light passes down the tube (via bundles of optical fibres) to illuminate the relevant area, and the video camera magnifies the area and projects it onto a television screen so the doctor can see what is there. Usually, an endoscope is inserted through one of the body's natural openings, such as the mouth, urethra, or anus.

7. Specially designed endoscopes are also used to perform a range of surgical procedures, such as:

    - Locating, sampling or removing tumours from the lungs and digestive tract.
    - Locating and removing foreign objects from the lungs and digestive tract.
    - Taking small samples of tissue for diagnostic purposes (biopsy)
    - Removing stones from the bile duct.
    - Placing tubes (stents) through blockages in the bile duct, oesophagus, duodenum, or colon.

8. Endoscopes have been developed for many parts of the body. Each has its own name, depending on the part of the body it is intended to investigate, such as:

    - Bronchoscope – inserted down the trachea (windpipe) to examine the lung.
    - Colonoscope – inserted through the anus to examine the colon (bowel).
    - Gastroscope – inserted down the oesophagus to examine the stomach.
    - Duodenoscope – inserted through the stomach into the duodenum to inspect and perform procedures on the bile duct and /or pancreatic duct, called ERCP (Endoscopic Retrograde Cholangio-Pancreatogram).
    - Hysteroscope – inserted through the cervix to examine the uterus.

- Cystoscope and ureteroscope - inserted via the urethra to inspect the urinary bladder and ureters.

9. The manufacture of endoscopes is dominated by large multi-national companies, particularly Olympus which dominates the market for flexible endoscopes with ~95% market share in Australia.

UNNECESSARY BARRIERS TO REPAIR

10. The market to repair and maintain endoscopes is dominated by the Original Equipment Manufacturers (OEM). The OEMs still largely operate in a closed repair, service and maintenance environment. Third party biomedical engineering services and repair organisations are a threat to lucrative recurring revenue streams.

11. These manufacturers commonly offer maintenance contracts, on a notionally "discounted" basis, at the time of selling scopes. For example, one leading OEM sells new equipment with an extended warranty and service program which can be for up to 3-4 years. OEMs routinely undercut third party repairers (as a loss leader) to attract new sales and disincentivise customers from repairing equipment. This bundling/tying allows the OEM's to leverage their dominant market position into what would otherwise be competitive aftermarkets. As outlined below, the OEMs use other strategies to foreclose competition in aftermarkets: e.g. refusing to supply parts; restricting information and restricting training. Such conduct was observable in other markets, such as automotive repair, until regulatory intervention.

12. In general, the useful life of a scope is in the order of 5-7 years (use dependent). For the past two upgrades, the market-leading OEM ensured that new equipment was not compatible with previous systems in their family of products (connections and use), and so a complete swap-out of customers' fleets of equipment were required (plus new service contracts). Customers who have a fleet of equipment at or beyond the life of the service contract are targeted for new equipment.

13. Some OEMs routinely inform customers that any repairs undertaken by third party service agents will void their warranty and the customer will not be covered under any agreements in place with the OEM. MDS understands that, if third party repairs are found by certain OEMs (no matter how minor), a complete rebuild will be quoted; indicatively at approx. $20 - $30,000 depending on the model. This is usually more than the residual value of the scope, resulting in a new purchase.

14. MDS understands that some endoscope OEMs actively promote the view that the workmanship of third-party service providers is sub-standard, is not undertaken with OEM parts and components (which are unavailable to third parties) and is not performed by trained personal, a practice of scaring the market. While, in some cases, concerns may be valid, they are certainly not universally true – any more than it could be said that every independent car mechanic is unable to provide services to the same standard as manufacturers and/or compromises public safety.

Closed access to parts, components and equipment

15. Part of the way OEM companies protect their business is to close access to the parts, components and equipment needed to undertake repairs.

16. MDS has made many attempts to purchase parts, components and equipment from OEMs and these have been flatly rejected.

17. OEMs have been known to use the Therapeutic Goods Administration as justification for refusing access to parts; however, the TGA is well aware of the service that third party repairers provide:

    - For example, the TGA has published the following: https://www.tga.gov.au/publication-issue/problems-associated-unauthorised-repair-rigid-scopes

    "The TGA's Incident Reporting and Investigation Scheme receives reports about the safety and performance of medical devices as part of its ongoing monitoring of products supplied in Australia. As part of this process the TGA has recently reviewed several reports associated with repaired endoscopes. These reports relate to the quality of the repair and the use of unsuitable parts. ***The TGA recognises that medical device repairers provide a useful service in assisting healthcare facilities to maintain good quality medical devices. However, it is important that healthcare facilities who require repairs to be made to medical devices, such as endoscopes, should satisfy themselves that the repairers have an appropriate level of training and experience to be able to competently undertake the repair work."***

18. It is also worth noting that the medical device regulatory framework includes provision for post-market monitoring by the TGA, including:

- risk assessment and investigation of medical device adverse event and complaint reports
- checking evidence of conformity against the Essential Principles
- conducting periodic inspections of manufacturers' quality management systems and technical documentation
- imposing specific requirements for manufacturers and sponsors to report, within specified timeframes, adverse incidents and other information involving their medical devices.

19. Post-market monitoring by the TGA is carried out to ensure the ongoing regulatory compliance and safety of medical devices supplied to the Australian market.

Training and information

20. OEMs are also unwilling to offer training or other support for third party repair and maintenance providers.

Efficiency losses arising from restricting third party repairs

21. There is an efficiency loss is forcing third party repairers to work around the restrictions imposed by dominant OEMs.

22. By way of example, MDS repairs and maintains endoscopes, and has an 18 year track-record of repair history in Australia, having saved the public healthcare system millions of dollars to date. With fleet maintenance contracts in place with a number of hospitals, MDS has over 600 scopes under contract.

23. MDS is currently the only third party repairer of medical endoscopes that was successful in the Biomedical Technology Services (BTS) Queensland tender for medical endoscopes and has repaired over 100 different scopes to date for the QLD Public health system.

24. MDS' "Total Care- Philosophy" can be summarized as:

- Repair in Australia, back to clinical specification, providing actual costed repairs.
- Reduce–The cost of rigid and flexible scope spends by extending the life of a hospital's fleet.

- Retrain–Targeted training for problem sites to reduce risk, downtime and increase customers knowledge for the care and maintenance of their equipment.

25. "Clinical specification" is the standard MDS works to at all times. This standard ensures that all scopes that leave MDS' facility have verified leak testing, hermetically sealed joins via laser welder, 28- point documented QA (etc) to ensure the scopes are fit for use in theatre.[1]

26. MDS does not only repair scopes, but it also identifies recurring issues and has a fleet inspection and training program to reduce common mistakes that result in costly repair bills. MDS's trained representatives will go on site and leave customers with a complete overview of the state and health of their current scope fleet. This service gives hospitals complete oversight of their fleet risk profile and what is involved to get it back to 100%. MDS often hears that "We have never been trained on this by the OEM."

27. As a repairer, MDS offers a very competitive service with the ability to diagnose actual faults and repair a single component, or as few components, as necessary. In contrast, most OEMs replace entire sub-assemblies in offshore facilities, increasing costs and repair times dramatically. MDS simply fixes what is wrong with a scope and no more.

28. Many OEMs do have loan fleets available but, in contrast, MDS has a loan fleet of over 100 scopes in Australia to help its customers.

29. MDS has obtained ISO 9001 and is in the process of obtaining ISO13485:2016 certification. MDS adheres to AS/NZ 3551 which is the Australian Standard for the Management program for medical equipment.

30. In terms of parts availability, in many aftermarkets parts availability is delineated in the following terms:

- **OEM Parts**: parts manufactured by the OEMs' parts suppliers
- **OEM supplier branded parts**: parts made by the same manufacturers as the 'genuine' parts (above) but the supplier uses their own company branding. (Same part, same manufacturer, different box)

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1 "Clinical specification" is a term that, in essence, means the endoscope is fit for clinical use, and its functions and specifications all meet the necessary thresholds, having been tested and verified for QA .MDS notes that OEM specifications are, in most aspects, accessible. Despite this, MDS has been threatened with legal action by an OEM for use of the term "OEM specification" because the OEM does not provide training to third parties or provide them with manufacturer data.

- **Independent Aftermarket Parts**: replacement parts that are manufactured specifically for use after the endoscope is built: These are quality, fit for purpose, interchangeable parts with the same functionality as the OEM part but produced by a different manufacturer to the OEM supplier.

31. As stated above, MDS is not able to access OEM parts. It is also unable to source OEM supplier branded parts (since the OEMs take steps to prevent the identity of component manufacturers becoming known). Hence, MDS uses Independent Aftermarket Parts – having secured the best possible repair components and technologies for all components including from USA, Germany, China, Taiwan and other countries. MDS only uses parts from component manufacturers with both ISO 9001:2008 "Manufacture and distribution of micro-optical components for the medical device, industrial, laser and telecommunications industries" and/or ISO 13845:2016 "Medical Devices". These parts come with 20 years of R&D, matching them to the closest possible dimensions and quality in respects to the OEM equivalents.

32. As a Medical Device Distributor, MDS further understands the importance of patient safety and all external parts that come in contact with a patient have biocompatibility, toxicity and safety certificates to ensure they are patient safe.

33. AS/NZS 3551:2012 Clause 1.4.56,b, specifically allows for the use of non OEM parts defined as:

    1.4. Spare part
    A substitute item, intended to replace an original component, assembly or subassembly of medical equipment, where the item is either—
    (a) a direct replacement (generally supplied, or specified, by the original equipment manufacturer (OEM)); or
    (b) an equivalent assessed by the service entity as being a suitable replacement for the original component contained in the medical equipment (which is not necessarily sourced from the OEM), and which is essential for the safe and correct operation of the medical equipment.

34. Furthermore, Section 9 (b)(i) states:

    Repair of medical equipment
    Repair of medical equipment using components not sourced from, or approved by, the original equipment manufacturer (OEM) constitutes a modification of the medical equipment. If the decision is taken to use non-OEM sourced components, then care shall be exercised to ensure that the

specifications of the alternative parts are equivalent in all respects. For spare parts or accessories considered critical to the safe operation of the medical equipment, any decision to use non-OEM supplied replacements, including the risk assessment undertaken in making the decision, shall be documented and retained as part of the medical equipment record for the device.

35. As a guide, a 'critical component' is considered to be one whose failure might reasonably be expected to cause the failure of a critical device or to affect its safety or effectiveness and potentially result in death or injury to a patient, user or other person. MDS does not replace any components "whose failure might reasonably be expected to cause the failure of a critical device or to affect its safety or effectiveness and potentially result in death or injury to a patient".

36. MDS matches the technology and techniques used in scope manufacture including: state-of-the-art laser welding, gold plating ability, 20-point inspection process QA, ISO Certified repair service and blinded QA. MDS can repair virtually all makes and models of endoscopes including semirigid and offset rigid scopes, with over 3000 models in its database. If they cannot repair to OEM -brand new condition they do not attempt to and will return the equipment.

37. MDS also:

- has trained 15 specialist technicians to work in its business;
- employs a head technician who was trained at a leading OEM and has 25 years of service history on rigid and flexible endoscopes;
- employs technicians who have received training from OEMs, and who are also highly educated with Bachelor of Technology (Mechanical Engineering), Post Graduate Diplomas in QA – Manufacturing & Management, and Bachelor of Electrical Engineering

LEGAL ISSUES

38. As the Productivity Commission is probably aware, competition issues associated with market conduct in aftermarkets have been considered extensively by regulators and by the courts in the United States and the

European Union. They have not received the same attention in Australia, although the ACCC is well aware of the issues.[2]

39. In June 2017, the OECD held a roundtable on "Competition issues in Aftermarkets" to compare national approaches to a number of questions that can arise under competition law when aftermarkets are involved. The papers from that roundtable are available on the OECD's website.[3]

40. Various aspects of the conduct experienced by MDS as a third-party repairer of endoscopes has parallels in conduct that has been considered in other countries. For example:

41. The Eastman Kodak case:[4] In 1987 seventeen small companies filed an antitrust lawsuit against Eastman Kodak. These companies, several of them small businesses, had been trying to compete with Kodak for contracts to provide maintenance service to end customers who owned expensive, durable Kodak photocopier or micrographics equipment. This case concerned Kodak practices relating to parts for, and maintenance service on, micrographic equipment and high-volume copiers. Ultimately, Kodak's restrictive parts policies were held to be anti-competitive, and Kodak was held liable for $24 million in damages, trebled to $72 million. On February 15, 1996, the district court issued a 10-year injunction requiring Kodak to sell parts to ISOs at non-discriminatory prices. This decision was upheld on appeal by the Ninth Circuit Court of Appeals.

42. In European automotive markets, the obligations to supply parts have been, since 2010, set out in four key legal instruments: the Automotive Block Exemption Regulation (EU) No. 461/2010; the sector-specific Guidelines on vertical restraints in agreements for the sale and repair of motor vehicles and for the distribution of spare parts for motor vehicles; the Vertical Restraints Block Exemption Regulation (EU) No. 330/2010; and the general Guidelines on vertical agreements. In effect, these instruments are designed to ensure effective competition in the markets for spare parts and equipment. Vehicle manufacturers may not hinder their original equipment suppliers from also supplying their products as spare parts to independent distributors or directly to independent or authorised repairers. Part producers also supply the independent aftermarket with spare parts of higher quality than the original equipment, or with parts 'fit for purpose' and adapted to the age of the

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2 E.g. ACCC, "Agricultural machinery: After-sales markets. Discussion Paper", February 2020; New car retailing mark study 2017; Merger authorisation sought by AP Eagers Limited in respect of its proposal to acquire Automotive Holdings Group Limited. Authorisation number: MA1000018 and associated submissions.

3 https://www.oecd.org/competition/aftermarkets-competition-issues.htm

4 Eastman Kodak Co. v. Image Technical Services, Inc., 504 U.S. 451 (1992).

vehicle; these of course fulfil all legal requirements, notably those contained in the product safety and environmental legislations. Importantly, spare parts producer may not be hindered from placing their own trademark on a part (either exclusively or in parallel as "double branding").[5]

43. In the Australian automotive industry, the ACCC has noted that "car manufacturers have an incentive to limit access by independent repairers to technical information to steer service work to authorised dealers and repair work to preferred repairer networks. This impacts "the ability of independent repairers to effectively and efficiently compete in the aftermarkets for the repair and servicing of new cars". It is also causes detriment to consumers in the form of increased costs, inconvenience and delays when having their new car repaired or serviced. The ACCC has noted that few car manufacturers provide equivalent access to the technical information provided to their authorised dealers and preferred repairer networks, and many provide very little or no information at all".[6]

44. In medical device markets analogous to that in which MDS operates, the Turkish Competition Authority (TCA) investigated medical device suppliers for excessive pricing and refusal to deal allegations in aftermarkets. It concluded that brand-specific aftermarkets constituted the relevant markets in the case and each supplier was dominant in its aftermarket. The suppliers were found to use encryptions and not supply the spare parts to independent service providers. In order to inject competition into secondary markets, the TCA obliged the suppliers (i) to provide the encryption key (the key to first level technical service, not ones that could contradict proprietary rights) for after-sale repair and maintenance for free after the guarantee term ends and upon the written request of the customer in 24 hours (ii) to supply or rent the equipment or devices necessary to provide after-sales services to customer or the service provider upon the written request/consent of the customer on non-discriminatory and cost pricing basis (iii) to inform customers about the above conditions at product purchase phase on written notice (iv) to respond customers' and service providers' price requests; (v) to act in a non-discriminatory manner to customers and service providers on supply of spare parts; (vi) to publicly announce the price list for the top 100

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5 See https://www.automarketexperts.eu/data/uploads/files/useful/r2rc-newberframeworkbrochure.pdf. Contrast this with certain OEMs' conduct, where it goes to extensive means to keep confidential the identity of its component and parts suppliers.

6 https://www.accc.gov.au/system/files/New%20car%20retailing%20industry%20final%20report_0.pdf

commonly used spare parts (based on the sales for the last three years) on its website.[7]

45. The purpose of this submission is not to comment on the adequacy of current Australian competition laws. MDS simply notes that the conduct of the OEMs today gives rise to a number of potential legal concerns, including:

- misuse of market power (refusal to supply; foreclosure through bundling/tying)
- entering into restrictive agreements with component manufacturers and, potentially, customers; and
- misleading and deceptive conduct (e.g. in promoting the incorrect view that third party repair and maintenance of endoscopes gives rise to safety and potential performance issues).

46. If we can assist you by providing further information, please let us know.

[7] https://one.oecd.org/document/DAF/COMP/WD(2017)54/en/pdf.