Reprocessing/Refurbishing Regulated Products: Responsibilities of Manufacturers, Users and the Regulator

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Key Questions:

- Who is responsible for what happens to a device after it is sold?
- By what means can reprocessing and refurbishment be monitored and managed?
Some Important Definitions

- Reprocessing - after use the device is cleaned, sterilized, repackaged for subsequent use
- Refurbishing – replacing or fixing parts on a device to allow it to be reused
The Technologies

- Reusable, including:
  - Simple, easily cleaned devices with few components
  - High cost, high complexity technology with intricate components
  - Limited use devices
- Single-Use
The Risks

Infection
- Transfer of bodily substances
- Bacterial growth
- Contamination by cleaning chemicals

Reduced Efficacy
- Deterioration
- Degradation
- Mechanical failure
Who is responsible for what happens after a device is sold?

- Purchasers (institutions)?
- Healthcare professionals?
- Manufacturers?
- Third party service providers?
- Regulators?
By What Means Can/Should Reprocessing and Refurbishment be Monitored and Managed?

- Regulation
- Litigation
- Contracts
- Intellectual Property Protection
Monitoring/Managing Reprocessing and Refurbishment

- Regulation
- Litigation
- Contracts
- Intellectual Property Protection
Regulation & The Division of Powers

- Federal Regulation
  - Spending and criminal powers
  - Sale and labelling of health products

- Provincial Regulation
  - Hospitals and property and civil rights powers
  - Delivery of health care
Federal Regulation

Addresses:

- Labelling and directions for use (which includes reprocessing)
- Sale
- Off-label promotion

Does Not Address:

- Use (of single use or reusable devices)
Provincial Regulation

Addresses:
- Licensing and standards for healthcare professionals and hospitals

Does Not Address:
- Third party reprocessing
- Sale
Monitoring/Managing Reprocessing and Refurbishment

- Regulation
- Litigation
- Contracts
- Intellectual Property Protection
Basis For A Claim

- **Negligence:**
  - Breach of a duty to exercise reasonable care in respect of persons affected by your actions
  - Requires:
    - Duty of care
    - Breach of standard of care
    - Causation
    - Damages
Healthcare Facilities

- Hospitals clearly owe a duty to their patients
- Hospitals must provide safe systems:
  - appropriate systems to assess patients
  - proper and functioning equipment and facilities
Healthcare Professional

- A clear duty owed
- In providing care must:
  - Obtain informed consent
  - Meet industry standards
Manufacturer

- Duty is clearly owed to first patient
  - Reusable: duty to provide appropriate cleaning instructions
  - Single Use: duty to communicate single-use status?
- What is the standard of care?
- If injury results from reuse, was that injury caused by the manufacturer’s conduct?
Third Party Service Providers

- Duty is owed not just to customer, but to the patient
- What is the applicable standard?
- Note: this would apply to in-house reprocessing by hospitals
Regulators

An up-hill battle

- Duty of Care – must establish that there is a duty to the individual, not just the public as a whole
- Public Policy – difference between policy decisions and operational decisions
Monitoring/Managing Reprocessing and Refurbishment

- Regulation
- Litigation
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Role of Contract

- Allocate risk
  - liability to hospital
  - liability to patients

- Shortcomings
  - no contract nexus (or “privity”) with patients
  - typical provisions inadequate
Manufacturer’s Liability

- Only if instructions followed
  - no liability if reprocessed
  - no liability if reprocessing causes harm

- Under standard representations, warranties and indemnities, manufacture **may** avoid liability for failure to use as instructed
  - an exception to representation, warranty and indemnity (avoiding liability to hospital under contract)
  - damage caused by hospital, or third-party processor (avoiding liability to patients)
- Interpretation issue (if exception is not explicit)
- Problem of causation (proving harm caused by reprocessing)
Tailored Contract Provisions

- Clear exception to representation/warranty/indemnity
  - expressly limit liability if reprocessing occurs
  - separate liability limitation
- No liability if reprocessing caused harm to patient
  - problem of proving causation
- No liability if reprocessing occurs (regardless of harm caused)
Liability to Patient

- No privity
- Impractical to warn or get waivers
Limiting Liability to Patient (Preventing Reprocessing)

- Prohibition against reprocessing
  - may shield from liability (defence or claim against reprocessor)
  - May not be enforceable
- Refusal to sell
- Termination for breach
Limiting Liability to Patient (Preventing Reprocessing)

- Indemnity from hospital
  - if any reprocessing causes harm
  - if any harm caused by reprocessed device (regardless of whether reprocessing caused)
BPS Procurement Directive

- Mandatory requirement to use form of contract provided with RFP
- Breach of law by hospital/purchasing agent may expose them to liability to unsuccessful bidders
  - limits ability to negotiate favourable contract terms
Monitoring/Managing Reprocessing and Refurbishment

- Regulation
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- Contracts
- Intellectual Property Protection
– The IP Landscape
The BIG Picture

A Patent

- The protection afforded a new and useful unobvious invention that is not anticipated by prior art
- A utility patent
- A process, composition of matter, method or means patent
The BIG Picture

A Design Patent or Industrial Design

- The protection afforded the novel non-functional ornamentation applied to a physical object
The BIG Picture

A Copyright

- The protection afforded an original expression reduced to a tangible form
A **Trade-Mark** (*Trade Mark, Trademark etc.*)

- The protection afforded to a word, logo, slogan, shape of packaging and the like that serve as a demarcation of the source of origin of your products or services.
The BIG Picture

A Trade Secret or Confidential Information

- An element of your business or its processes that you do not disclose except in a circumstance of confidence
Integrated Circuit Topography or Masked Works Rights

- The protection afforded to the architectural design of an integrated circuit
Intellectual Property Law as an Instrument of Trade Economics


- *Fish, J, in obiter states:*
  
  Without so deciding, I express grave doubt whether the law governing the protection of intellectual property rights in Canada can be transformed in this way into an instrument of trade control not contemplated by the *Copyright Act.*
The BIG Picture

- The most effective intellectual property protection programs contemplate the layering of intellectual property rights
Enforcing patent rights to address reprocessing and refurbishing medical devices depends upon whether:

- the reprocessed/refurbished device is the subject itself of an enforceable patent; or
- The reprocessed/refurbished device is a component of a larger combination that is patented
Repair versus Reconstruction

- Patent rights are infringed in Canada when a person interferes with the full enjoyment of the monopoly granted to the patentee

- The owner of a valid Canadian patent has the exclusive right to make, manufacture, construct and sell the invention
  - S.42 of the *Patent Act (Canada)*
  - This has been interpreted to include the right to import the patented invention into Canada – see *Wellcome Foundation Ltd. v. Apotex Inc.* (1990) 32 C.P.R. (3rd) 350
Repair versus Reconstruction

- No element of a claimed combination that is not separately patented is entitled to a patent monopoly.
- A purchaser of patented articles possess an implied license to have those articles repaired, and may procure replacement parts.
Repair versus Reconstruction

- There is no bright line between permissible repair and infringing reconstruction

- Is the existing product being maintained or is the end result a new article

- A case by case determination to assess whether the essence of the invention is being remade as opposed to maintained
Repair versus Reconstruction

- Underlying the determination is the competition law concept of *exhaustion of patent rights*

- An unrestricted sale of a patented article by or with the authority of the patent owner, “exhausts” the patent owner’s right to control further sale and use of the patented invention, by enforcing the patent under which it was first sold

- In order to call the monopoly conferred by the patent grant into play for a second time, it must be a second creation of the patented item
Repair versus Reconstruction

- Permissible repair may encompass replacement of a spent unpatented components, in order to maintain or preserve the utility for which the patented item was originally intended.

- Thus, for patent infringement purposes, product notifications like SINGLE USE ONLY are helpful but not determinative.
The Liability of the Reprocessor

- Unlike the U.K. and the U.S., Canada has no statutory provision defining the scope of indirect infringement - so-called inducing patent infringement or contributory patent infringement.

- Sometimes in Canada the reprocessor can be considered a direct infringer with its customer.
The Liability of the Reprocessor

- In Canada, case law has defined the scope of indirect infringement as comprising three elements

- First, there must be a direct patent infringement somewhere in the chain
The Liability of the Reprocessor

- Second, the indirect infringer must induce or exercise influence over the direct infringer such that the infringement would not have taken place without that influence
  - this is more than simply making the infringing component

- Third, there must be a degree of knowledge residing with the inducer (the act must be committed knowingly)
  - knowledge that the inducer is exercising influence is a companion to the second element
  - However, knowledge of the actual patent infringed does not appear to be required - see, for example, *Bauer Hockey Corp. v. Easton Sports Canada Inc.* (2010), 83 C.P.R. (4th) 315, aff’d 2011 FCA 83
Strategies for Enforcement

- Consider a conscientious patent program, that includes, where possible, the unique design and patenting of key components, and not just their combination.

- While not determinative, it is helpful to mark the patent reference and the non-reusable status of the item, on the product and its packaging.
  - May assist with knowledge component when seeking to enforce against an indirect infringer.
Strategies for Enforcement

- Consider including claims in patents that specify different embodiments, such as reusable and non-reusable versions of the invention and key components.

- Where practicable, embed other IP rights such as embossed trade-marks, unique product industrial design and shaping, and copyrights to embedded instructions and interface software.
Strategies for Enforcement

● While aggressive, in appropriate circumstances consider licensing a device for single use only, as opposed to the outright sale of the item

● Where the business model contemplates substantial revenue from the supply of wasting components, consider the lease/license, as opposed to sale, of the device and the patenting of the replacement component
  ● Perhaps coupled with favourable lease terms based upon volume purchase of the patented replaceable component
Thank You