TUKAKIRA ET AL v. HOPITAL LA CROIX DU SUD ET AL

[Rwanda HIGH COURT – RCA00321/2016/HC/KIG, RCA00320/2016/HC/KIG, RCA00322/2016/HC/KIG, RCA00336/2016/HC/KIG (Kabagambe, P.J.) September 29, 2017]

Damages – Tort liability – The claimant for damages due to the prejudice suffered must prove the causal link between the prejudice and the fault commited.

Liability – Product liabilities – Pharmaceutical product liability – A lincenced pharmaceutical is liable for the negative effects caused by the defective drugs which he/she imports – Decree law of 30/07/1888 relating to tha contracts or obligations, article 259 and 260

Facts: After, HOPITAL LA CROIX DU SUD treated Tukakira, Mutesi, Bayitake and Rubagumya with ndlr lidocaine 2% injection , they suffered the negative effects, this led them to sue the hospital to the Intermediate Court of Nyarugenge claiming to be reimbursed the expenses they incurred in the treatment of those effects, transport fees spent during the treatment, damages for the pain suffered after the injection of lidocaine 2%, moral damages, procedural fees and damages for being dragged into lawsuits.

HOPITAL LA CROIX DU SUD requested that SONARWA G.I.CO. Ltd, its insurer and ABACUS Pharma Rwanda Ltd which supplied lidocaine 2% that was injected to the plaintiffs be summoned as warrantors; the Intermediate Court found their

claim with merit in part and held that ndlr lidocaine 2% which was injected to them caused them negative effect, that there was no professional fault committed by HOPITAL LA CROIX DU SUD when administaring that drug. Therefore, the hospital as well as SONARWA G.I.CO. Ltd are not liable, then it found ABACUS Pharma Rwanda Ltd liable because it is the one which sold ndlr lidocaine 2% injected to the plaintiffs, thus it ordered it to pay the requested damages.

All the plaintiffs as well as ABACUS Pharma Rwanda Ltd were not satisfied with that decisions and appealed to the High Court contesting the basis of those damages and how they are calculated.

At the High Court, the issues analysed were the causal link between ndlr lidocaine 2% injection batch CM 4032 and the negative effects suffered by those who were injected and whether the requested damages should be awarded.

In its defense, ABACUS Pharma Rwanda Ltd stating that the previous Court based its decision on the fact that lidocaine 2% used was of substandard quality, but it disregarded that even if it was true, a causal link between lidocaine 2% injection and the negative effects suffered by patients had to be established, it further argues that it produced before the court enough elements of evidence which proves that the causal link between the negative effects suffered by plaintiffs and injection of lidocaine 2% batch CM 4032 was not proved beyond reasonable doubt.

Tukakira, Mutesi, Bayitake and Rubagumya argue that the Court considered the casual link between the seller and user of the lidocaine 2%, and also ABACUS PHARMA LTD must guarranty the safety of its products.

HOPITAL LA CROIX DU SUD states that all plaintiffs on the first instance experienced negative effects after being injected, this demonstrates the causal link of the injection of lidocaine 2% and there are also elements of evidence including various reports from different laboratories proving that the drug which they were injected does not meet the required standard, therefore, ABACUS Pharma Rwanda Ltd should be held liable for the negative effects caused by lidocaine 2%.

The ministry of health was asked about the procedure in case the lincenced pharmaceutical imports defective drugs and it responded that the lincenced pharmaceutical is liable for the effects caused by that drug.

Held: 1. The claimant for damages due to the prejudice suffered must prove the causal link between the prejudice and the fault commited. Basing on the test conducting by the various experts, the ndlr lidocaine 2% which ABACUS Pharma Rwanda Ltd supplied to HOPITAL LA CROIX DU SUD did not meet the required standard and it is the one which caused negative effects to the plaintiffs. Therefore, ABACUS Pharma Rwanda Ltd should be held liable for the effects caused by ndlr lidocaine 2%.

2. Moral damages resulting from negative effects caused by that drug are awarded in the discretion of the court since there is no specific Law regarding their calculation

3. HOPITAL LA CROIX DU SUD should not pay damages for not taking proper care of the plaintiffs because it did not commit any professional fault, rather the faults were committed by ABACUS Pharma Rwanda Ltd because it is the one which supplied the defective drug.

The appeal lacks merit.
The Court fees deposited by the appellants is equivalent to the costs of the case

Statutes and statutory instruments referred to:
Law N°15/2004 of 12/06/2004 relating to evidence and its production, article 3 and 9.
Decree Law of 30/07/1888 relating to contracts or obligations, article 258, 259 and 260.

No case referred to.

Judgment

I. BACKGROUND OF THE CASE

[1] This case started in the Intermediate Court of Nyarugenge Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent suing HOPITAL LA CROIX DU SUD, claiming to be reimbursed the cost for the treatment of illness and wounds which were due to the hospital's fault and to be refunded the transport fees spent during the treatment as follows: Tukakira Rugigana Deus 9,607,047Frw, Rubagumya Clinton Innocent 230,025Frw, Mutesi Scola 383,212Frw and Bayitake Angelique 375,879Frw. They also requested damages due to the pain suffered after the injection of lidocaine 2% (anaesthesia)which caused the wounds as follow: Tukakira Rugigana Deus 200,000,000Frw, Rubagumya Clinton Innocent 100,000,000Frw, Mutesi Scola 150,000,000Frw, Bayitake Angelique 150,000,000Frw; for the moral damages, they claim that Tukakira Rugigana Deus be

awarded 100,000,000Frw, Rubagumya Clinton Innocent 50,000,000Frw, Mutesi Scola 50,000,000Frw, Bayitake Angelique 50,000,000Frw; procedural fees and damages for being dragged into lawsuits 3,000,000Frw for Tukakira Rugigana Deus, 1,000,000Frw for Rubagumya Clinton Innocent, 1,000,000Frw for Mutesi Scola, 1,000,000Frw for Bayitake Angelique and lastly Tukakira Rugigana Deus and Rubagumya Clinton Innocent requested to be given 2,992,428Frw, and 160,000Frw respectively for the financial loss they incurred.

[2] At the request of HOPITAL LA CROIX DU SUD, SONARWA G.I.CO. Ltd the insurer of HOPITAL LA CROIX DU SUD and ABACUS Pharma Rwanda Ltd which a supplied lidocaine 2% to HOPITAL LA CROIX DU SUD were summoned by the Court as warrantors.

[3] The Intermediate Court of Nyarugenge found the case of Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent with meritin part, and held that ndlr lidocaine 2% which was injected to Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent caused them health problems and it also held that there was no professional fault committed by HOPITAL LA CROIX DU SUD when it used ndlr lidocaine 2% to treat the plaintiffs, that HOPITAL LA CROIX DU SUD and SONARWA G.I.CO.Ltd are not liable, therefore, ABACUS Pharma Rwanda Ltd is liable for the damages resulting from ndlr lidocaine 2% injected to Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent, the court ordered ABACUS Pharma Rwanda Ltd to pay damages and counsel fees to the plaintiffs as follows:

21,184,153Frw to Tukakira Rugigana Deus; 3,158,106Frw to Rubagumya Clinton Innocent; 4,251,641Frw to Mutesi Scola and 4,224,908Frw to Bayitake Angelique. The Court also ordered ABACUS Pharma Rwanda Ltd to reimburse 4,883,604Frw to HOPITAL LA CROIX DU SUD, futher, it declared that ABACUS Pharma Rwanda Ltd does not deserve damages ; and lastly ordered ABACUS Pharma Rwanda Ltd to refund Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent, 50.000Frw to each for court fees.

[4] ABACUS Pharma Rwanda Ltd appealed to the High Court contesting the basis of those damages while Tukakira Rugigana Deus, Mutesi Scola and Bayitake Angelique appealed contesting how they were calculated.

Issues to be examined in this case :

- **Whether there is a causal link between ndlr lidocaine 2% injection batch CM4032 and negative effects suffered by those who were injected**
- **Whether damages should be awarded in this case**

II. ANALYSIS OF THE ISSUES

A. Whether there is a causal link between ndlr lidocaine 2% injection batch CM4032 and negative effects suffered by those who were injected

[5] The counsel for ABACUS Pharma Rwanda Ltd pleads that the court based its decision on the fact that lidocaine 2% used was substandard quality, but it failed to consider that even

if it was true, a causal link between the fault and prejudice suffered had to be established as it was demonstrated during the hearing but the court disregarded it whereas it was contrary to the general principles as advanced by law scholars[1] and it was raised during the hearing.

[6] The counsel for ABACUS Pharma Rwanda Ltd states that in the analysis of this issue,the court disregarded with no reasons several evidence presented before it demonstrating that the causal link between the the negative effects suffered by the plaintiffs and lidocaine 2% batch CM4032 which they were injected as an anaesthesia was not proved beyond reasonable doubt.,because the case file at first instance contains a list made by ABACUS Pharma Rwanda Ltd which indicates where that medicine was sold countrywide,which was disregarded by the court, though itwas informed of it because it held that "the fact that Viateur Mutanguha, the counsel for ABACUS states that the lidocaine 2% was sold to other clinics and hospitals countrywide without causing negative effects, the court finds that statement without merit since he does not demonstrate where the medicine was used and to whom it was injected".

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[1] https://fr.wikipedia.org/wiki/Responsabilit%C3%A9_du_fait_des_produits_de_sant%C3%A9_d%C3%A9fectueux *:« afin d'engager la responsabilité du fait d'un produit défectueux, la victime doit prouver la défectuosité du produit, le dommage subi ainsi que le lien de causalité entre la défectuosité du produit et la survenance du dommage. En effet, ce lien de causalité doit être certain…. La preuve du lien de causalité…admet la possibilité de recourir à des présomptions graves, précises et concordantes. Ces présomptions ne seront admises que si trois conditions sont réunies. En premier lieu, le fait doit pouvoir être matériellement une cause génératrice du dommage à l'égard des données acquises de la science. Egalement, il doit être hautement probable que le facteur ait été à l'origine du dommage. Enfin toutes les autres causes de possibles du dommage doivent avoir été exclues »*

Therefore, the Court deliberately did not consider the evidence which was aimed to prove the doubt cast on affirming that the lidocaine 2% batch CM4032 caused negative effects to only 4 people treated in one hospital (Hopital la Croix du Sud) which was supplied only100 fl while that sold in the whole country is 4282 fl de 30ml.

[7] After realising that issue which had occured at Hopital la Croix du Sud, in order to prevent the same issue, ABACUS Pharma Rwanda Ltd requested all clinics and hospitals to return back lidocaine 2% batch 4032 bought, but only the hospital of Gitwe returned 50 fl in 69 fl that it had bought and it did not report any negative effect on the patients who were injected with other19fl which appears in its report. Hopital la Croix du Sud bought 100 fl of lidocaine 2% batch CM 4032, but after realizing the issue with that lidocaine 2%, it was also requested to return the remaining vials that were not yet used, but it didn't, one wonders that may be the remaining vials were used and did not cause any effect to patients. Therefore given the above reasons and legal principles that "the same causes produce the same effects", there is doubt cast on the assertion that lidocaine 2% batch CM 4032 caused negative effects to only 4 patients out of 8564 to whom it may have been injected.

[8] The counsel for Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent states that the Court considered the casual link between the seller and user of the lidocaine 2%. It means ABACUS PHARMA LTD must guarranty the safety of its products. If a consummer is harmed by its products, ABACUS PHARMA LTD is held liable. Therefore, they find that the court did not err in its decision of awarding damages because the wounds suffered by

the plaintiffs resulted from the lidocaine 2% injection bought from ABACUS PHARMA LTD.

[9] The counsel for Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent argues also that ABACUS PHARMA LTD ackwnoledges that it is the one that sold lidocaine 2% that caused a negative effects to the plaintiffs and after being aware of the safety issue, it immediately recalled that drug in order to prevent its use on other patients; since it admits that it is the one which sold lidocaine 2% that was administered to the patients as anaesthesia and caused negative effects as demonstrated by the photos and medical reports, it implies that it sold unsafe drug.

[10] On the assertion that the decision of the Court does not demonstrate the casual link between the injection of lidocaine 2% BATCH CM4032 and the negatives effects caused, the counsel for HOPITAL LA CROIX DU SUD argues that ABACUS did not bring expert to contradict the reports provided by Rwandan and foreign laboratories so that if necessary that expert can be questioned by the court or cross examined by plaintiffs. Furthermore, the causal link is demonstrated on the first page, section one, whereby all plaintiffs on the first instance state that within a short period after being injected with lidocaine 2%, they experienced negative effects, this demonstrates the causality of the drug injected. Futhermore there are other elements of evidence proving that the anaesthesia injection was not safe as indicated by various reports : 1) The first report dated 15/04/2015 made by the laboratory of University of Rwanda which indicates that in physico- chemical test on the third point called Asssay, the drug has 94.1 while it should be between 95.0% -105.0 %. Thus, the laboratory

concluded that the drug does not meet the required standard. 2) The second report was made by SGS laboratory of waver in Belgium on 19/08/2015 and this laboratory is recognized by WHO (World Health Organization), this is also emphasized by a report of LINCOLN PHARMACEUTICALS company that produced Lidocaine injection 2%, whereby it indicated that BATCH CM4032 sold to ABACUS PHARMA can cause negative effects which includes : allergies and necrosis. Therefore, since even the company that sold the drug declared that it does not meet the required standard, and ABACUS went ahead and bought that drug, it is the one to be held liable. They find all these are corroborative and enough evidence to prove that the drug was defective and that it is the causal link between the wounds and the lidocaine 2% that caused those effects to the plaintiffs at the first instance, this report indicates that the lidocaine 2% is 94.5% while it should be between 95.0% and 105.0%, the report concluded that the drug is "fail"!

[11] The Court summoned a specialist in pharmaceutical from the Ministry of Health and Semana Edmond together with legal advisor of that Ministry appeared before the Court, the court also summoned the CEO of HOPITAL LA CROIX DU SUD appeared together with Kwizera Gad, a laboratory scientist all were summoned to provide information on the Lidocaine injection 2%.

[12] Semana Edmond told the court that pharmaceutical depots and health institutions are the only authorized importer of drugs, they have the certificate of origin attesting that its fulfils the required standard and also they have to demonstrate that the manufacturer fulfils the requirements to manufacture drugs; he further stated that there is a list of drugs authorized in

Rwanda, and when drugs are brought into the country the supplier is allowed to sell at retail to, health institutions, once the drug is in their stock, doctors can prescribe it to the patients. Besides that all those how are involved in that chain must take good care of the drug and kept at the required temperature, lest it gets spoilt, well, they must also keep a record indicating the origin of the drugs in purposely to trace their origin in case of any problem. Regarding the procedure of recalling the drug he explained that when it is reported that a drug has caused a negative effect it immediately ceases to be prescribed to patients, and they trace its origin and call the importer, and ask him where he supplied it and where it caused those negative effects and the causes.

[13] Semana Edmond further explained that the Ministry was informed of the negative effects caused by Lidocaine injection 2%, where it happened and where it was bought, then the Ministry visited that hospital where that issue was reported and suspended that batch number from the market, it also suspended the use that drug. He added that in Rwanda the authorized drugs are those of Pharmacopoeia 5: USP (US Pharmacopoeia), BP (British Pharmacopoeia), European Pharmacopoeia, JP (Japanese Pharmacopoeia), Pharmacopoeia international. In case of testing the drug, they have to check the register, that is, if the drug is BP the testing will be conducted in accordance with the registrer of British Pharmacopoeia. In addition if they find the drug with a defect it is permentaly removed from the market and all is done after carring out enough examinations.

[14] Semana Edmond explains that in regard to the quality of drugs, a the drug meets the required standards or is below or above the standard of the manufacturer or of the

Pharmacopoeia, that a drug which is below or above the set standards of the Pharmacopoeia then that drug is defective, and if the colour is not the same it also implies that it is defective. And furthermore, there is the quality which can be ordinary observed and that which requires to first be tested. But in Rwanda there is no laboratories to examine the quality of drugs. The equipments used to dispense the drugs must also be examined if they meet the the required standard.

[15] Semana Edmond was asked what happens when a lincenced pharmaceutical importer brings defective drugs, and he responded that those various categories which deal in drugs are the ones liable, however the first category to be held liable is the one from whom that damage occurs often they request to burn those drugs. Pharmaceutical depots are usually inspected first, scrutinizing the certificate and the batch number, because a manufacturing company can supply the same drug to various places but each with its own batch number, then they determine whether it is the pharmacy or hospital to be held liable. Semana Edmond was asked the opinion of the Ministry of Health on Lidocaine injection 2%, he replied that they only went to Hopital la croix du sud because it is the only place where that issue occurred, there was no other complaint in other places where that that batch was supplied. Semana Edmond was again asked as a ministry of health, when they requested that Lidocaine injection 2% be examined whether it was examined in accordance to the pharmacopoeia or not, he replied that the requested expertise should have been conducted in accordance with pharmacopoeia, but unfortunately it was not the case.

[16] Counsel Gumisiriza states that the Ministry of Health called for an examination of Lidocaine injection 2% which

caused the health problems. But he wonders what the Ministry did when it realized that the expertises were not conducted in accordance to pharmacopoeia.

[17] Counsel Mutanguha states that the Ministry of Health, at the request of HOPITAL LA CROIX DU SUD, asked laboratories to carry out the examination, and it was the employee of that hospital who requested the use of the British Pharmacopoeia, if they did not notice which Pharmacopoeia used, that is negligence. It is groundless doubting the methods used by the experts by alleging that the expertise was carried out basing on USP (US Pharmacopoeia) while the drug was produced basing on BP (British Pharmacopoeia).

[18] Counsel Muhozi Paulin prays to the court to hear the testimony of Kwizera Gad an employee in the laboratory who participated in all expertises, so that his statements can corroborated with those of the representantive of the Ministry of Health.

[19] Kwizera Gad, an employee of the Hopital la croix du sud, who is pursuing his masters in Pharmacology, explained that it is the hospital that communicated on the issue, the Ministry of Health instructed them to carry out an expertise,it gave them the laboratories from where it could be carried out, they first requested the expertise to be carried out in Africa: Uganda, Kenya, South Africa and those of Suitzerland and France,but they all replied that they were not ready to conduct the expertise even though their laboratories are accredited by WHO. He further states that the hospital requested that the expertise be based on British Pharmacopoeia because it is the one written on the drug, but it was told that an experise can be carried out basing on the US Pharmacopoeia even thought the

drugs were produced basing on British Pharmacopoeia. And also, the laboratory of Butare and that of Belgium advised them to use US Pharmacopoeia.

[20] Kwizera Gad goes on stating that it depended on the methods used in administering that drug those who were injected in superficial method got ngative effects he added that there is also another drug bought by CAMERWA which also caused negative effects to extent that some patients died. Even when a drug meets the required standards it has to continuously to be followed up. In addition to that, he explains that there is a hospital near by where Lidocaine injection 2% was administered on the patient's eye and he suffered negatives effects, he notes that the Ministry of health needs to put more emphasis on pharmaco vigilance. There are 60 vials of the drugs which caused those effects kept purposely to continue carring out more examinations, because the parts on which it was injected would be burnt and would turn whitishand again the person injecting that drug would change and use another vial whenever the patient told told him or her that he is feeling pain and again he felt the pain even after using another vial and moreover those who were injecting the patients are trained doctors.

[21] The CEO of HOPITAL LA CROIX DU SUD, Nyirinkwaya Jean Chrysostome, explained they bought lidocaine 2% in February, which was injected to patients and felt the pain, after identifying the issue, they immediately reported it to the Ministry of Health to avoid the same issue in other hospitals. They went to Butare to examine that drug, they found a Lidocaine with defect and other which meet the required standard, and apparently are different, then the

Ministry of Health ordered them to go to make a test of the drug in other laboratories, hence, they went to Belgium, Kenya and South Africa, the results were similar to those of the laboratory of Butare. Moreover, they bought 2 lots of the lidocaine 2% but they only used a half of the one with a defect.

[22] Counsel Mutanguha states that HOPITAL LA CROIX DU SUD did not return all lots it bought, and that Safari is still working in the hospital while he was not allowed to treat his wife. In addition, a nurse who examined Rugigana declared that when he urinates, he felt pain at the head of penis.

[23] Counsel Muhozi states that Safari was the head of the emergency service, it would be diverging to talk about professional fault while the issue is the drug administered.

[24] Dr Nyirinkwaya argues that the arguments of counsel Mutanguha are not relevant to the issue of the drug.

[25] Counsel Rutagengwa states that the examination of Lidocaine carried out in Butare and Belgium, but he wonders how the experts could get the real result by using a wrong formula, he adds on that Abacus Pharma knows the truth, but it is just being in different; and it alsowrote to the company that manufactured the drug; he wonders how the company contradict itself and declares that its drug was defective.

[26] Counsel Gumisiriza submits that there is no doubt that SGS has the capacity to detect a defective drug, even if other laboratories conduct the test, they can refuse to recognize them while ABACUS and LA CROIX DU SUD had already agreed that the lidocaine 2% may be defective ; that ABACUS should not state that the expertise done by manifacturer laboratory is

the one which is right because the latter does everything to match the drug with the requirements. He further argues that the claim that there is no evidence to prove that the negative effects was caused by drug is baseless because when the patient complained that was feeling the pain instead of being numb when injected. Therefore, they find that the liability orginates from the drug at hand which caused injuries. Besides, the drug has expired and cannot be tested in laboratory.

[27] Counsel Mutanguha states that ABACUS PHARMA affirms Lidocaine BP 2% that it meet the required standard, it does not also agree with those who say that they got health problems caused by injection of that drug because the tests which were conducted had a lot of flaws because they did not follow the proper standards as explained above .and there is no concrete evidence to prove that those negative effects were caused by Lidocaine BP 2%.

[28] Counsel Muhozi states that Abacus Pharma should have demonstrated that it criticized those reports from the beginning, thus, he requests the court to consider those reports since Abacus has its headquarters in India, it is not understable how it can come to contradict the reports made by the Ministry of Health.

VIEW OF THE COURT

[29] According to article 3 of the Law relating to evidence and its production provides that each party has the burden of proving the facts it alleges. According to article 9 of the law same law provides that an evidence based on legal issues or on fact can be proved by use of written evidences, testimony,

presumption or circumstancial evidence, admission of a part or any other material evidence.

[30] In accordance with article 258 of the Law 30 july 1888 establishing civil code (CCBIII) provides that any act or omission by man that causes another injury, requires that the former, due to the wrongly act commited, to repair it.

[31] In accordance with article 259 of the Law of 30 July 1888 establishing civil code book (CCBIII) provides that a person is not only liable for his acts, but also for his negligence

[32] The court finds that the party which claims for damages for the prejudice suffered must prove the causal link between the prejudice and the fault commited.

[33] The court finds that Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent sued for damages resulting from the wounds sustained when they were injected with ndlr lidocaine 2% by HOPITAL LA CROIX DU SUD The court finds that HOPITAL LA CROIX DU SUD demonstrated that there was no proffessional fault on its part when it was treating Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent because the sickness and wounds were caused by ndlr lidocaine 2% injection which they bought from ABACUS Pharma Rwanda Ltd. The Court also finds that ABACUS Pharma Rwanda Ltd acknowldges that it is one which supplied ndlr lidocaine 2% injection to HOPITAL LA CROIX DU SUD which was administered to Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent.

[34] The court finds that the medical report issued by HOPITAL LA CROIX DU SUD on 25/05/2015 indicates that on 22/02/2015 Rubagumya Innocent, born in 1995 went for a nail surgery of ingrown toe nail of the right big toe whereby he was injected an anaesthesia of Lidocaine HCI injectable BP 2% on the toe of the right foot, thereafter he experienced a toe ache (*necrose cutanee avec oedeme du pied*), they thought the ache was caused by the anaesthesia injection and this was confirmed by the laboratories that examined that drug.

[35] The court finds that the medical report issued by HOPITAL LA CROIX DU SUD on 25/05/2015, Bayitake Angelique, born in 1979, went for the treatment (*ablation de Kyste sebacé thoracique anterieur*) to that hospital and an anaesthesia lidocaine HCI injectable BP 2% was administered to her and she felt tremendous pain on the part of the body which had to be treated (*necrose du site d'infiltration par l'infirmier et le dermatologue*) to the extent that she received treatment for 2 days, they thought the ache was caused by the anaesthesia injection and this was confirmed by the laboratories that examined that drug.

[36] The court finds that the medical report issued by HOPITAL LA CROIX DU SUD on 25/05/2015, indicates that on 21/02/2015, Tukakira Rugigana Deus, born in 1983, went there requesting for circumcision, for that reason he was injected an anaesthesia (Lidocaine HCI injectable BP 2%) and traeted, he was given an appointment to return to the hospital on 24/02/2015, on that day they found that his prepuce had been affected (a dry necrosis of the prepuce).They thought it was caused by the anaesthesia injected on him and this was confirmed by a laboratory that tested that lidocaine 2%.

[37] The court finds that the medical report issued by HOPITAL LA CROIX DU SUD on 25/05/2015, indicates that on 20/02/2015 Mutesi Scola,born in 1985, went for the treatment (removal of subcutaneous hormonal implant in the left arm) to that hospital and an anaesthesia lidocaine HCI injectable BP 2% was administered to her and she felt tremendous pain on the part of the body which had to be treated (necrose seche cutanee localisee) to the extent that she received treatment for 2 days, they thought the ache was caused by the anaesthesia injection and this was confirmed by the laboratories that examined that drug.

[38] He finds that the report issued on 15/04/2015 by the University of Rwanda indicates that lidocaine 2% (Batch No.CM4032 LINCOLN PHARMACEUTICAL, INDIA) did not meet the required standard[2,] and it is that was injected on

[2]University of Rwanda, college of Medicine and health sciences laboratory of analysis of foods, drugs, water and toxics, reports analysis: conclusions: " parameters that been analyzed are the pH, identification and assay, bacterial endotoxins, sterility test and research of impurities, following conclusions are be made: the pH is normal, there is no presence of bacterial endotoxins, sterility is negative and results are given in annex I of this report.
Chromatographic analysis of Lidocaine HCI injection B.P 2% (Batch No.CM4032 LINCOLN PHARMACEUTICAL, INDIA) both concentrated and diluted samples reveal impurities which are normally present when comparing with Lidocaine injection BP 2% samples from other manufactures. The UV spectrum has been found but we are unable to identify which molecule he is. We suggest that the client to send (submit) to other laboratories for further identification with advanced technique like IR or NMR.
Chromatographic analyses of Lidocaine HCI injection B.P 2% (Batch No. E0889, MAC'S PHARMACETICAL. Nairobi, KENYA) both concentrated and diluted samples reveal the presence of a second excipient Propyl Paraben in the product which it presence is not labelled or indicated in the vial of Lidocaine HCI injection B.P 2%; The UV spectrum and the retention time of

Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent.

[39] The Court finds that the report issued by SGS (Life science services) on 19/08/2015 also indicates that ndlr lidocaine 2% (identification: No.CM4032) was defective[3] . And it is the same drug which was injected to Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent.

[40] The Court finds that the reports presented are proofs attesting that ndlr lidocaine 2% (Batch No.CM4032 LINCOLN PHARMACEUTICAL, INDIA) which was injected to Tukakira Rugigana Deus, Mutesi Scola, Bayitake Angelique and Rubagumya Clinton Innocent was defective.

[41] The Court finds that the medical legal report issued by King Faisal hospital Kigali indicates that: Mutesi Schola has incapacity of 8%[4]; Tukakira Rugigana Deus has of incapacity

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Propyl Paraben containing the sample match with those of reference standard. We recommend the client not to use it without ensuring that it can adverse effect to patients (not conform to Lidocaine HCI injection B.P 2%).
As requested by the client, research, identification, assay and research of impurities has been done. However, these impurities have not been identified due to lack more advanced techniques of detection"

[3]SGS, CERTIFICATE OF ANALYSIS, Product: Lidocaine Hydrochloride Injection, USP, identification: CM4032, Qty Rec'd : 7, received date : 24/7/2015. "The residue obtained responds to identification test A under Lidocaine: pass. Test: pH, Method: USP <791>, specification: 5.0 -7.0, result: 6.6, status: pass. Test: Assay, Method: USP, specification: 95 -105.0 % LC, result: mg found 20.1mg/ml, Assay 94.5 % LC, status: fail.

[4] her inability to work is estimated at 2 months and the permanent incapacity is evaluated at 8%.

estimated at 30%[5] while Rubagumya Clinton Innocent his incapacity is at 3%[6].

[42] The court finds that the arguments of ABACUS Pharma that the test was erroneous because it did not follow the standards of pharamacopeia are baseless, because those reports were made on the request of the Ministry of health and ABACUS Pharma did not object to them, nor demonstrate to the Ministry of health what it object in those report even the ministry of health did not raise an objection against that those report.

[43] In accordance to article 260 of the third book of the the civil code, which provides that one is responsible not only for the damage one causes by one's own act, but also for that which is caused by the act of persons for whom one is responsible or things which one has under one's care.

[44] The court finds that ABACUS Pharma that is liable for the negative effects caused by Lidocaine HCI injectable BP 2% which it sold to Hopital La croix du Sud, which the experts indicated it was defective, it caused negative effects to the patients who went for treatment in Hopital la croix du sud, who later on sued in previous Court. Therefore, the court finds that

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[5] "Erectile dysfunction due to the initial extensive penile skin necrosis, the subsenquent multiple surgeries and penile curvature. The sexual incapacity is evaluated at 80% today. The permanent physical incapacity is estimated to 30%. NB: the definitive sexual and physical incapacity will be most accurately estimated after additional corrective plastic surgery for penile curvature as suggested by the treating plastic surgeon."

[6] " his inability to work is estimated at 45 days and the permanent incapacity is evaluated at 3% ».

there is no error committed by the previous Court in deciding that Abacus Pharma is liable.

B. Concerning the requested damages

a. Assessment of the amount of moral damages to be awarded in this case

[45] The Counsel for Mutesi Scola state that basing on photos which indicate the pain suffered and its effects, she had requested for 150,000,000Frw. He was astonished for the Court to hold that, it was excessive, they failed to find the Court's basis for awarding only 3,000,000Frw. They request the High Court to award all requested damages amounting 150,000,000Frw.

[46] The counsel for Bayitake Angelique state that that basing on photos which indicate the pain suffered and its effects, she had requested for 150,000,000Frw. He was astonished for the Court to hold that, it was excessive, they failed to find the Court's basis for awarding only 3,000,000Frw. They request the High Court to award all requested damages amounting 150,000,000Frw.

[47] The Counsel for Tukakira Rugigana Deus state that considering the pain suffered as indicated on the photos, would have led the court to award him all the damages claimed. They pray that the High Court awards all the damages requested.

[48] The Counsel for ABACUS PHARMA RWANDA Ltd states that the Court awarded damages without tangible evidence, the Court awarded them basing only on the photos produced by the defendants to indicate the pain and wounds suffered. Also, the photos neither indicate the time, place they

were taken, nor the person who took them so that they can be considered as tangible evidence, as provided for by article 122 of the law relating to evidence and its production.

[49] The counsel for Hopital La croix du Sud state that there is no standard measurement of the pain, it is the reason why the Court should base its decision on tangible evidence produced by the plaintifs and in the Court's discretion regarding the recent photos, they may not be real as they are not accompanied by a doctor's report, another evidence which can be based on is the medical report.

VIEW OF THE COURT

[50] According to article 258 of the Law 30 july 1888 establishing civil code (CCLIII) provides that any act or omission by man that causes another injury, requires that the former, due to the wrongly act commited, to repair it.

[51] In accordance to with article 260 of the third book of the the civil code, which provides that one is responsible not only for the damage one causes by one's own act, but also for that which is caused by the act of persons for whom one is responsible or things which one has under one's care; it is.

[52] The Court finds that the reports provided by HOPITAL LA CROIX DU SUD demonstrated by the plaintiffs got health problems as result of lidocaine 2% as also demonstrated by the reports from King Faysal Hospital. Regarding the amount of damages in this case, there is no specific Law regarding their calculation, therefore, they are calculated at the discretion of the Court.The court finds that the claimants for damages did not

demonstrate the basis of the amount of the damages they request for, even in their appeal they did not demonstrate why the damages awarded to them should be increased. Therefore the lower Court did not err in calculation of damages it awarded.

C. Whether HOPITAL LA CROIX DU SUD should pay damages for neglecting the defendants

[53] The Counsel for Tukakira Rugigana Deus, Mutesi Scola and Bayitake Angelique state that HOPITAL LA CROIX DU SUD should be held liable for having neglected its clients who are the plaintiffs in this case because it should have followed up and treat them before spending time trying to establish the cause. Hopital la CROIX DU SUD should pay the claimed damages by the plaintiffs for neglecting them because thier sickness was caused by the Hospital, it is after the injection that they suffered from its negative effects. HOPITAL LA CROIX DU SUD should pay these damages for neglecting its patients because, even before the Ministry of health was informed of the issue which happened in the Hopital CROIX DU SUD, and before taking the drug for testing in the laboratories and even informing ABACUS PHARMA Ltd about the drug it sold, they should have been treated first. The fact that the hospital did nothing, while the plaintiffs were running everywhere seeking for treatment without enough means, the hospital did not inform them what it was doing about it, for them to have courage, so they find that the hospital should be held liable for neglecting its patients and pay the damages for that as follows : Tukakira-100,000,000Frw, Mutesi Scola- 50,000,000Frw and Bayitake Angelique-50,000,000Frw.

[54] In its defense, Hopital la croix du Sud argues that that after knowing the problem the patients got, it carried out an

investigation and its findings were used as evidence that the court relied on, those evidence was found on the expense of the Hospital as it is evident on the page 6 paragraph 15 of the judgement copy, there are 3 elements of evidence prooving that the drug was the cause of the plantiffs's health problems and no due to professional fault.

VIEW OF THE COURT

[55] According to article 258 of the Law of 30 July 1888 establishing the civil code book III (CCBIII) provides that any act or omission by man that causes another injury, requires that the former, due to the wrongly act commited, to repair it.

[56] The Courts finds that the plaintiffs did not demonstrate any professional fault on the part of Hopital la Croix du Sud, because as indicated above, it is ABACUS Pharma Rwanda Ltd that was held liable because of its drug which caused the negative effects to the plaintiffs. Therefore, the damages requested from the hospital are irrelevant, the previous Court did not err in deciding that the hospital was not liable.

D. Concerning procedural and counsel fees

[57] The Counsel for ABACUS Pharma Rwanda Ltd states that they claim for procedural fee of 500,000Frw, counsel fee of 1,000,000Frw and moral damages of 2,000,000Frw and 3,000,000Frw for libel and being dragged into uncessary lawsuit.

[58] The counsel for HOPITAL LA CROIX DU SUD state that they lodge a cross-appeal basing on article 167 CPCCSA, they request the court to order Tukakira Rugigana Deus, Mutesi

Scola and Bayitake Angelique to pay 200,000Frw for procedural fee and 1,000,000Frw for counsel fees.

[59] The Counsel for Tukakira Rugigana Deus, Mutesi Scola and Bayitake Angelique request the Court to order the respondents to reimburse them Court fees, counsel and procedural fees.

VIEW OF THE COURT

[60] The court finds that ABACUS Pharma Rwanda Ltd does not deserve damages because its appeal has no merit. The Court finds that the damages claimed by HOPITAL LA CROIX DU SUD against Tukakira Rugigana Deus, Mutesi Scola and Bayitake Angelique should not be awarded because it is their right to appeal. The damages claimed by Tukakira Rugigana Deus, Mutesi Scola and Bayitake Angelique should not also be awarded because their appeal lacks merit.

III. DECISION OF THE COURT

[61] Admits the appeal lodged by Tukakira Rugigana Deus, Mutesi Scola and Bayitake Angelique, upon its examination, it finds it with no merit.

[62] The Court admits the appeal lodged by ABACUS Pharma Rwanda Ltd, after its examination, but it finds it with no merit.

[63] The judgment RC0828/15/TGI/NYGE rendered on 03/06/2016 by the Intermediate Court of Nyarugenge is sustained.

[64] Declares that the Court fees deposited by the appellants is equivalent to the costs of the case